EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL WAVE 4 AND SUBSEQUENT WAVE CASES	)	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

DEPOSITION OF STANLEY ZASLAU, M.D.

Wednesday, March 8, 2017

General- Prolift

General - Gynemesh PS

DEPOSITION OF STANLEY ZASLAU, M.D. a witness herein, called by the Plaintiffs for examination, taken pursuant to the Federal Rules of Civil Procedure, by and before Constance Lee, a Registered Professional Reporter and a Notary Public in and for the State of West Virginia, at the law offices of Jackson Kelly, PLLC, 150 Clay Street, Suite 500, Morgantown, West Virginia, on Wednesday, March 8, 2017, at 2:01 p.m.

COUNSEL PRESENT:

For the Plaintiffs:

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PROCEEDINGS

STANLEY ZASLAU, M.D.

a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. FAES:

Q. Good afternoon, Dr. Zaslau.

A. Good afternoon, sir.

Q. My name is Andy Faes, and I represent various Plaintiffs in this litigation, and I'm here now to take your deposition regarding the Prolift and Gynemesh PS products. Do you understand that?

A. I do.

Q. And you understand that you're under oath and must tell the truth; correct?

A. I understand.

Q. And I know you've been through this several times before but if I ask you a question that for some reason you don't understand, please let me know, and I'll try to rephrase the question. Okay?

A. Okay.

Q. I'm going to hand you what's been marked as

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Exhibit No. 1 to your deposition. Have you seen this before?

(Dr. Zaslau Deposition Exhibit No. 1 was marked for identification.)

A. Yes, I have.

Q. And this notice asks you to bring various documents and things to your deposition today.

A. Yes.

Q. Have you brought anything with you in response to the request in this notice?

A. I brought a variety of things, yes.

Q. What did you bring?

A. A copy of my CV, and that's it.

Q. Just your CV?

MS. ROBINSON: May I interrupt.

MR. FAES: You may.

MS. ROBINSON: I just provided you with a flash drive that includes all of his reliance materials which are the materials that were provided to you in response to his notice of deposition.

MR. FAES: I'm going to mark that as Exhibit No. 5, the flash drive, and I'll probably come back to that in just a second.

(Dr. Zaslau Deposition Exhibit No. 5 was

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marked for identification.)

Q. First, Doctor, I see you have a binder in front of you with various materials.

A. Yes.

Q. What's in that binder? I'll let you answer the question: What's in the binder that you brought with you today?

A. It has a variety of different studies, exhibits from other depositions, materials I've reviewed, articles.

Q. Okay. I'm going to hand you what's been marked as Exhibit No. 2 to your deposition. Can you tell me what that is.

(Dr. Zaslau Deposition Exhibit No. 2 was marked for identification.)

A. That is my general expert report.

Q. And this report is the report that you signed on January 11th of this year; is that accurate?

A. Yes.

Q. And does this report in front of you marked as Exhibit No. 2 contain all of the opinions that you've reached regarding the Prolift and Gynemesh PS products?

A. To the date as of January 11th, the date that

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it was signed, yes.

Q. And in this report you go through various facts and discuss various facts. Did you discuss the facts that you felt were most relevant and important to you in drawing your opinions in this case?

MS. ROBINSON: Object to form.

A. I did, yes.

Q. There are also many various articles cited throughout your expert report; correct?

A. Yes.

Q. In terms of your decision-making in writing your report, why did you cite to those articles?

A. I thought they had scientific importance. I believed the paper was sound and the conclusion and the recommendations were sound.

Q. So it's accurate that you believe all of the articles that you specifically discuss in the body of your report are relevant and the conclusions of those articles are sound; is that accurate?

A. I think the material is relevant, yes. And I think the conclusions are sound.

Q. Okay. I'm going to hand you what's been marked as Exhibit No. 3 and 4 to your deposition.

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(Dr. Zaslau Deposition Exhibit Nos. 3 and 4 were marked for identification.)
MR. FAES: That's 3. That's 4.
Q. And can you tell me what Exhibit No. 3 is.
A. Exhibit 3 is a general reliance list in addition to materials that I have in my report that I've written on Gynemesh and Prolift.
Q. Okay. And what is Exhibit No. 4?
A. Exhibit No. 4 are supplemental additional materials in addition to what was referenced and reported in my report.
Q. Actually, can I ask you to hand me back Exhibit No. 4 because that's my copy. I'm going to get you a different Exhibit No. 4.
MR. FAES: For the record, it's the same No. 4. It's just a copy without my markings on it.
(Witness reviews document.)
Q. Do you -- do you know what the difference is between Exhibit No. 3 and Exhibit No. 4?
A. Yeah. There's certainly additional materials in it. The latter parts of No. 4 refer to videos, to a deposition comment, to questions from the FDA, a lot of expert reports, a variety of different physicians over a period of time.

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Q. So do you know specifically or -- strike that.
Do you know in general what kinds of materials were added to Exhibit No. 4, your supplemental reliance list? Did I understand you correctly that you added some procedure videos to that?
A. Yeah, it looked like there were some procedure videos and discussions that are in here as well. There's a large, large body of material here.
Q. And when did you review the additional materials that were added to your supplemental reliance list marked as Exhibit No. 4?
A. I've been reviewing materials in preparation for this report and additional materials, very significantly over the last three months, to as of last evening.
Q. Now, counsel has brought with her a flash drive marked as Exhibit No. 5.
A. Yes.
Q. Is there anything contained on Exhibit No. 5 that is not listed in your supplemental reliance list marked as Exhibit No. 4?
A. No, there shouldn't be anything different.

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Q. Is there anything in the binder that you brought with you today that's in front of you that is not on -- listed in the reliance list marked as Exhibit No. 4?
A. No.
Q. Now, I noticed on your reliance list there is a lot of literature regarding slings and TVT and TVT-O. In forming your opinions regarding the Prolift and Gynemesh PS, did you rely on midurethral slings and the TVT to form any of your opinions regarding the safety and efficacy of the Prolift?
A. Yes.
Q. What specifically did you rely on?
A. The design of the TVT is what helped create the eventual Prolift; the trocars, the mechanism for which they could be inserted, the concepts of the anatomy and their relevant relationships leads to the use of trocars in the pelvic floor, from the original TVT when it came out in 1997 to its modifications via the obturator route.
Q. And the same question regarding the Gynemesh PS product: In forming your opinions regarding the Gynemesh PS product, did you rely on midurethral slings, specifically the TVT and TVT-O to form any

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of your opinions regarding the safety and efficacy of the Gynemesh PS?
A. Yes. Again, certainly, it was those formatives studies, that formative product, that helped lead to the discovery of Gynemesh PS.
Q. Are you relying on any data or findings in any of the TVT or midurethral sling literature in order to form your opinions regarding the Prolift?
A. Yes.
Q. And what are you relying on there?
A. Well, we've known about the success of slings since even before TVT was described. Back in the mid-1990s, and even before, with a variety of different types of mesh that was used and the way that mesh was delivered with not trocars at the time but staining needles.
So the procedure has -- of how that was done, the complications associated thereof, were the same issues that are certainly relevant to the TVT and later to the Gynemesh and Prolift.
Q. Would you agree that the -- the overall safety profile of TVT and TVT-O is different from the overall safety profile of Prolift product?
MS. ROBINSON: Object to form.

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A. I don't follow what you mean by "safety profile." What do you mean by that?
Q. Would you agree -- well, what do you believe a safety profile is? I guess when I say "safety profile" -- strike that.
What I mean "safety profile," I mean the overall safety and efficacy of the product. With that definition in mind, would you agree that the overall safety profile of the TVT and TVT-O is different from the Prolift product?
MS. ROBINSON: Object to form.
A. I'm not sure I'm understanding, but I'll try and answer.
Q. Okay.
A. To me, when you say "safety profile," what you're saying is that does the product do what it's intended to do, are the risks that could be associated with it predictable based on how it would work. And would the success be able to be predicted on the basis of both of those things, in other words, its mechanism and the complications that would be associated with. That's how I would see that.
Q. You'd agree that the, for example, the TVT

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product has much less mesh in it than the Prolift product; correct?
A. The TVT does have less mesh it in, yes.
Q. And you'd agree that the fact that the Prolift has much more mesh than the TVT and TVT-O product can mean that it can potentially cause a higher rate and incidence of complications than the TVT because of the amount of mesh present?
MS. ROBINSON: Object to form.
A. That would be expected on terms of the volume of mesh, yes. You could estimate that. For a TVT it would be, it's a 2-by-12 centimeter mesh. So of that, roughly 6 centimeters would be under the urethra and out laterally to the pelvic side wall. In Prolift or in a prolene mesh PS, a typical defect might be 6 centimeters by maybe 8 centimeters in terms of the width of the cystocele, so that's 48 cubic centimeters in terms of volume.
So I would expect that, since there's four times more mesh in the typical cystocele, that the rate of complication can certainly be magnified four or more times.
Q. Okay. When were you first contacted regarding being an expert on the Prolift and

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Gynemesh PS products?
A. I was asked originally to work in the TVT cases about four years ago. At that time there was discussion of involvement in the Prolift cases. But it was only over the last six months that I was asked to go forward and work and prepare formal reporting as I have for today.
Q. So if I understand your testimony correctly, you believe you started work on the -- your Prolift and Gynemesh PS report sometime in November of last year or December?
A. I started over the summer. I mean, this was -- was an ongoing discussion that there would be a need to work on a Prolift report. And this was based on the timing of when counsel had asked me to complete that and their discussion was to have it completed for the January submission.
Q. So I guess my question is when did you essentially get the green light, so to speak, from counsel from Ethicon and Johnson & Johnson to start working on a general expert report for Prolift and Gynemesh PS?
A. Over the summer of last year, initially, but the bulk of the work was really done over the last

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three to four months.
Q. Have you billed for any of that time yet for your Gynemesh PS and Prolift report beginning in the summer of last year?
A. Some of that has through monthly reports but there are other projects I am working on in this litigation. So it was a piece of a larger effort.
Q. Have you brought any of those invoices for your Gynemesh PS and Prolift with you here today?
A. I have not, no.
Q. How many hours would you -- and we've asked that those be produced.
How many hours would you estimate that you've spent working on review of materials and drafting your Gynemesh PS Prolift report?
A. Approximately 45 hours.
Q. And those 45 hours, were those at a rate of $500 an hour?
A. That's correct.
Q. How many hours would you say you spent actually drafting the report as opposed to reviewing materials?
A. I do both at the same time, so it's -- it's hard to tell. I may have on one computer an article

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I'm looking at and writing on my laptop, so sometimes they're both done at the same time.
Q. Is it fair to say that when you bill for your time, you don't separate your writing activities versus your review of material activities?
A. I do not.
Q. Okay. I'm going to hand you what's been marked as Exhibit No. 6 to your deposition.
(Dr. Zaslau Deposition Exhibit No. 6 was marked for identification.)
Q. If you can tell me what that is.
A. This is copy of my CV.
Q. Uh-huh. I'll represent to you that this is the copy that was provided to us with your expert report. Is this your current curriculum vitae?
A. Yes. I mean, certainly there may be some additional publications that may have been added since this had gone to you.
Q. When was this last updated?
A. I update it monthly, so I don't -- there's usually a date on the bottom. I can't see the date here. For whatever reason it was blocked out at some point in time. This was probably, I'd say, the January version, so you know, early January 2017,

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first week of January.
Q. And as you mentioned earlier, your curriculum vitae includes a list of publications.
A. Yes.
Q. Do any of those publications listed in your CV specifically address the Prolift product?
A. No.
Q. Do any of the publications in your CV specifically address the Gynemesh PS product?
A. No.
Q. Do any of your publications in your CV specifically address the TVM technique for the treatment of prolapse?
A. Yes, there's an article that we published in 2016 on the carcinogenic potential of mesh. I'm not sure if it made it into this version here. I could look and see. We've had several other case reports that were published regarding eroded -- eroded Burch and MMK procedures, which may not have made it into this version because they were just recently accepted.
Q. Okay. What -- what -- what's the name of the article where you discuss carcinogenic?
A. It's by Adel, A-D-E-L, 2016, and it's on the

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carcinogenic potential of mesh. I'm trying to see if I can find you the exact -- exact copy of it, which is somewhere in my reliance. It may be in one of these books. I'm not sure which exact one it's in, but let me see if I can find it. Yeah, Carcinogenic Potential of Polypropylene Midurethral Slings, What Do We Know So Far.
Q. Okay. And you mentioned earlier some case reports?
A. Yes.
Q. Regarding the MMK and the Burch procedure?
A. Yes.
Q. I understand those have been submitted for publication?
A. They were just accepted by the American College of Obstetrics and Gynecology resident case reviews. So these are case reports that were accepted for publication for their website.
Q. So was it one case report regarding one MMK and one regarding Burch?
A. That's correct, one of each.
Q. Those are treatments for stress urinary incontinence, not for vaginal prolapse; correct?
A. That's correct. But they were written

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because these were patients involving erosions of their materials.
Q. Why did you choose to write a case report regarding erosion materials from MMK and the Burch procedure?
A. These were patients that had these procedures many years ago and had other symptoms that were not addressed, and only upon cystoscopy were these issues noted.
Q. Have you ever published in the area of mesh complications?
A. Not directly, no.
Q. So you say not directly; have you published indirectly in the area of mesh complication?
A. I meant -- I should have just said no.
Q. Okay. So what did you mean when you said not directly? Were you perhaps referring just to your expert reports in this litigation or is there something else you were thinking of?
A. I don't know what I was thinking of.
Q. Okay. Now, you've used Prolift in your medical practice from approximately 2004 to 2012; is that correct?
A. Yes. Closer to 2010 or so. We didn't have

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access to it after about 2010.
Q. Okay. I'm just going by your expert report, which I believe says that you implanted approximately 100 Prolifts between 2004 and 2012?
A. Right. Really all of them -- Prolift was available nationally until about 2012, but at our facility, my last case was probably about 2009. Or so.
Q. Okay. Actually, it says on page 3 of your report it says from 2001 until 2012 you performed over 100 Prolift procedures. Do you see that?
A. Yeah. Well, I couldn't have performed them in 2001 because Prolift didn't exist in 2001.
Q. That's correct. When do you believe that you first performed a Prolift procedure?
A. On page 3, I started -- in the second paragraph, I learned to perform the Prolift procedure in practice beginning in 2004. So from 2001 to 2012 should really say, from 2004 on I performed a hundred Prolift procedures.
Q. So that's an error in your report on page 3 where it should say 2004 to 2012; is that accurate?
A. Yes.
MS. ROBINSON: Object to form.

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A. Yes.
Q. Where did you learn to -- where did you first -- strike that.
Where were you first trained on the Prolift device?
A. I went to the Cleveland Clinic to a hands-on session with Dr. Howard Goldman, it was a cadaver lab and live cases.
Q. Now, I don't -- correct me if I'm wrong, but is there anywhere in your expert report where you talk about the first time you used the Gynemesh PS product, specifically the flat mesh product?
A. I never used it as an independent entity. It's not been available at our hospital to use as an independent product.
Q. And you've been at West Virginia University since 2001?
A. That's correct.
Q. Do you know why it's never been offered at your hospital --
A. I don't know.
Q. -- as an independent product?
A. I don't know and I never asked.
Q. And to this day you've never asked; is that

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accurate?
A. Now, it's after the fact. You know, once the mesh kits had not been available, then, you know, why would I go back and ask? It also wasn't something that was necessary for me to use as an independent product.
Q. So do you -- you perform -- I know I'm going to say it wrong -- for the rest of day I'll refer to it as ASC, do you perform abdominal sacrocolpopexy with mesh products?
A. I do now, yes.
Q. What products do you use for ASC?
A. We use the Bard Y-mesh and have been using that for the last few years.
Q. So the Bard Y-mesh is available at your hospital, but the Gynemesh PS is not; is that accurate?
A. That's correct. It was never available, and I don't know why it wasn't or what the story was. The first Gynecare product available was the TVT, and the TVT-O certainly was available, and the Prolift was available. But Gynemesh as a separate entity wasn't.
Q. Do you know whether or not Ethicon and

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Johnson & Johnson makes a Y-mesh similar to the Bard ALYTE?
A. Yeah, I don't know if they do.
Q. Have you ever asked or done any research on that?
A. No, because this is, again -- our abdominal sacrocolpopexy experience is just over the last few years. So in terms of what's available to us, the Boston product is available.
I want to make one comment. I want to make a comment to you about our hospitals and how ordering works. The products are ordered through the system for not just our hospital but for others in the system. So they'll order things that maybe other people might use, and so they'll make decisions based on the system. Say, well, you're the only one using it for the system, you know, maybe we should use something else. They're using something else in Parkersburg, could you use what they use. They're trying to make systems decisions for a large number of hospitals. So that affects availability of what's available.
Q. What other mesh kits have you used for the treatment of pelvic organ prolapse?

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A. Just Prolift.
Q. Do you -- did you feel at the time that you used the Prolift from 2004 to 2012 that it was the best mesh kit available for the treatment of pelvic organ prolapse?
A. I liked it. I liked it because it was easy to use. It's a very logical approach. I liked that the mesh was soft and easy to position where you wanted to at the level of the defect. I was happy with it. And I had good results. It was very intuitively easy to do based on all that we knew already about trocars and placement in the body for 15 -- say, 2004 -- so for the -- my nine years prior, there was a logical extension.
Q. My question was a little different, though. My question was specifically, did you feel, when you were using the Prolift that it was the best mesh kit available for the treatment of pelvic organ prolapse?
A. I didn't look for others. I was happy once I had started using it and didn't feel I needed to look further.
Q. So if I understand you correctly, you don't have an opinion one way or the other whether or not

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the Prolift was the best mesh kit available for the treatment of pelvic organ prolapse when you were using it?
A. I haven't tried any other ones, so I couldn't tell you. But I was happy with the product I was using. So I didn't feel the need to try other ones.
Q. So do you intend to offer an opinion in this case that the Prolift mesh was -- is or was the best mesh kit available for the treatment of pelvic organ prolapse?
A. I think it's an excellent kit that serves -- served its stated purpose of what it was intended to do and was successful in its use and, to this day, I still see patients back who have done extremely well with it.
Q. Right. I think my answer (sic) is a pretty simple yes-or-no question. Do you intend to offer an opinion in this case, one way or the other, that the Prolift mesh kit is the best -- is or was the best mesh kit available for the treatment of pelvic organ prolapse?
A. I certainly couldn't say it's the best because it's the only one I've used, so I wouldn't have a fair comparison to another kit.

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Q. Do you have any opinions about whether or not the Gynemesh PS mesh is the best mesh available for the treatment of pelvic organ prolapse?
A. Again, I couldn't say it's the best mesh for its intended purpose of what it's supposed to do.
Q. I think you've answered my question. Go ahead and finish.
A. I was going to say for its intended purpose, it does quite well.
Q. So when was the last Prolift mesh that you implanted in a patient? When was that done?
A. I would say 2009 or 2010. Our hospital at that point had stopped ordering them. This was sometime after the FDA ruling in 2008. But for no reason other than -- well, we're not stocking this because you're the only one using this. I was the only one using Prolift. There's no one else using other mesh kits in our hospital. I'm not sure about any other ones in the system, but you're the only one using them. We're stocking them just for you.
Q. So you believe that the last time you implanted a Prolift mesh was in 2009 or 2010?
A. Yes.
Q. Not 2012, as stated in your expert report?

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A. No.
Q. On page 3?
A. I have not done anything after say 2010.
Q. So your report should read on page 3, from 2004 until 2009 or 2010, you performed over a hundred Prolift procedures?
A. Yes.
Q. And the -- you still believe that that part of the sentence is right, that you performed over a hundred Prolift procedures?
A. Just over a hundred, yes.
Q. How did you determine that you performed over a hundred Prolift procedures?
A. Well, we reviewed patients and how they're doing. Look at complications. Look at the kind of procedures we were doing and so that gave me that number.
Q. So the last time that you implanted a Prolift device was in 2009 or 2010; when was the last time that you performed a Prolift procedure?
A. 2009 or 2010.
Q. It was the same time?
A. Yes.
Q. And why did you choose to stop doing the

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Prolift procedure?
A. It wasn't available anymore in our facility.
Q. Okay. Just to clarify, Doctor, I'm asking about the Prolift procedure, not the Prolift device?
A. Right. I only used the Prolift device. I never used the Gynemesh. If the device wasn't there, then I didn't do the procedure or I couldn't do the procedure.
Q. So it's your testimony that you can't do a Prolift procedure without having the Prolift device?
MS. ROBINSON: Object to form.
A. Well, when you're saying the Prolift procedure, what you're saying to me is their trademarked procedure with their trocars and their mesh, and I'm saying that I can't since it's not available.
Q. Well, do you know that prior to the Prolift mesh kit being commercially available as a kit in 2004, that doctors were taking the Gynemesh PS mesh and cutting it themselves and essentially putting it in the same way or close to the same way as the Gynemesh -- strike that -- as the Prolift kit?
A. That's certainly something that could be done, that's certainly something I knew about, but

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chose not to.
Q. Why did you choose not to?
A. I liked the kit. It was very compact and easy to use. The handles were very ergonomic. The retrieval device was very logical and to come up and create something on my own, I just didn't think was good. Our hospital was trying to do the same thing with their slings: They have a general sling kit that you can fashion into whatever you wanted to do and it didn't go over well amongst any of the practitioners. So I decided I'm not going to manufacture something. I'm just going to go back to what is tried and true and it's what's worked and know that it's an option I don't have that's available to me.
Q. Is it fair to say that one of the reasons that why you chose not to continue to do the Prolift procedure once the Prolift kit was no longer available to you at your hospital is because you felt like there were better treatment options available to your patients?
MS. ROBINSON: Object to form. Mischaracterizes his testimony.
A. No, I don't think the treatment options were

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better. I think that these were the options that I was left with. If the Prolift were available, I certainly would have wanted to keep using it because it worked. It had done quite well. If you can't have what -- what you'd like to have, you can also do the things that work. I've done anterior repairs for many years with cadaveric fascia with fascia lata, with pericardium. Just traditional applications.
I have enough other options for prolapse that if I don't have a Prolift, I can work around it. But certainly it would have been nice to have. In those special cases where Prolift would have really been a great thing to have.
Q. So you mentioned that you've used cadaveric tissue for a prolapse repair; is that correct?
A. Yes.
Q. Have you ever used the cadaveric tissue in a Prolift-type procedure?
A. Yes.
Q. And you still do that today?
A. Not as frequently. I don't think it works as well. It depends on each patient. One of the things about prolapse is that every patient is

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different. They have multiple surgeries, the size of the prolapse, and all these factors need to be considered. The ideal biologic is still yet to be determined. I use Pelvicol a lot. Early on it was very thick. I didn't like the way it healed. There were ridges in it.
Fascia lata is good but not in every patient. Sometimes they had pain and other complaints. It's something that is really very individualized as to how to approach prolapse.
Q. When was the last time you performed a Prolift-type procedure using cadaveric tissue?
MS. ROBINSON: Object to form to the characterization of the Prolift-type procedure.
A. When you -- you refer to that several times. To, me when you say Prolift you're talking about trocars; and the answer is I don't use trocars anymore because they're not available and I'm not going to use a staining needle as a trocar. I won't. I will do sacrospinous ligament fixation with fascia using free needles or a Capio device or something. I don't use trocars anymore. I have not used trocars since the Prolift kit has not been available.

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Q. Prior to 2004 when you started using the Prolift device, what were you -- what were you doing to treat pelvic organ prolapse?
A. The same things that I had mentioned to you earlier. So anterior repair, anterior repair with autologous fascia as needed. With cadaveric fascia, with Pelvicol cadaveric dermis, Tutoplast Pericardium. Whatever options were available to us in our tissue bank.
Q. So in 2009 or 2010, when your hospital stopped having the Prolift available, did you ever go to the Prolift -- strike that.
Did you ever go to the hospital or the board or whoever is in charge of purchasing those things and say to them, hey, I really want to keep using this Prolift? Can I still get it?
A. I asked them what had gone on, and then they said, we're not stocking this anymore. You're the only one in the system who uses it. I didn't want to start putting up a fight over it as the only person who is using it.
I could go back to what worked. It worked fine before. This was nice, nice to have, nice in the right patient. But that's a sign of

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where they were. And I didn't fight that battle.
Q. So you felt that even without the Prolift product, there were plenty of other nonmesh alternatives that were suitable options that were available to you to treat your patients with pelvic organ prolapse; is that accurate?
MS. ROBINSON: Object to form.
A. Well, there are options that are available. Are they as good as Prolift is? Yes, I think Prolift would be just as good. But I do think that in particular cases, particular index cases that Prolift would be better. For larger defects, for multicompartment defects, it would be nice to have that. It would be nice to have that option for patients. But that option was taken away.
Q. But you'd agree that even without Prolift as an option you had sufficient acceptable alternative options to treat pelvic organ prolapse when your hospital stopped stocking the Prolift?
MS. ROBINSON: Object to form.
A. As I said, yes, they were good options but certainly it would be nice to have Prolift as well. If I can't have it, I can't have it. But it's -- that's the way it was.

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Q. Okay.
MR. FAES: I'm going to object and move to strike after the answer, yes, they were good options.
Q. During the time that you were using the Prolift from 2004 to 2009 or '10, did you continue to do native tissue repairs with sutures as an alternative to Prolift and vice versa or did you only do Prolift?
A. No, I did -- all of the above, as you mentioned. So native tissue repairs, application, cadaveric grafting. You know, Prolift was for special patients with special disease states.
Q. So what was your -- what was your patient selection criteria for using the Prolift during the time that you were using that device?
A. Patients with very large defects, large anterior defects or large posterior defects. Patients with very large multicompartment defects, so anterior as well as a posterior defect. Patients who had failed other procedures and maybe they were done from above. Maybe someone had an abdominal sacrocolpopexy and failed, so you don't want to go back in the same compartment so you go in from

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below. Patients who -- I was worried about had a risk of failure, of significant failure from multiple components.
Q. Is it fair to say that you generally only performed the Prolift in patients with stage 3 or 4 defects?
MS. ROBINSON: Object to form.
A. Four, it would depend on the age. Because in four you have to wonder whether you should do a colpocleisis and close off the vaginal vault. Some of those patients, you don't want to fix their prolapse, you would rather close the vault. Some stage 2, most stage 3.
Q. Did you ever perform a Prolift in a patient with stage 1 prolapse?
A. No.
Q. Do you feel it's appropriate to perform a Prolift in a patient with stage 1 prolapse?
A. I think you have to make that decision when you're in the OR. Sometimes what you gauge clinically is not what you see in the OR. So you think it's a stage 1, and you get to the OR and it's actually worse, then yes. Sometimes you get to the OR and you think it's a stage 2 and then once you

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unroof it there's a big enterocele, and there's a small cystocele, and so the answer would be no. You don't have to open the Prolift kit until you're ready to use it. So it's not something that's lost moneys for the institution if you don't open it. So you make the decision as you need to based on the individual patient.

Q. When did you first perform the ASC procedure?

A. I've done the ASC, I do these with our urogynecology colleague who doesn't like the morbidity of an abdominal incision, has concerns about the ureters and such, so I will help him with mobilization and setup and do all those cases.

Q. I don't want to interrupt you, Doctor. My time is limited. I just want to back you up a little bit because my question is a little different. My question was just, specifically, when did you first perform the ASC?

MS. ROBINSON: I think he was answering the question, and I think he's entitled to explain his answers.

Q. Were you answering my question? I think it would just be a year.

MR. FAES: It sounded like he was

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talking about one of his colleagues.

Q. Go ahead and finish your answer.

A. So in 2014, we began doing these regular with my colleague who doesn't like the morbidity of abdominal punctures and these challenging situations involving the ureter. So starting at that point I would be involved in all of those ASC cases. We do approximately two a month.

Q. Is it your testimony that you didn't first do an ASC until 2014?

A. Yes.

Q. I apologize. That's where the confusion was. I just figured you did one much earlier than that.

So is the Bard Y-mesh the only mesh you've ever used for an ASC procedure?

A. Yes.

Q. Do you feel that's the best mesh available when mesh is needed for an ASC procedure?

MS. ROBINSON: Object to form.

A. I think it works well for us. We have not had any erosions or extrusions that we know from it but I haven't tried others. We haven't felt the need to try others.

Q. In terms of alternative treatments for a

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patient, ASC would be one of the alternatives if there was, in fact, prolapse in the part of pelvis that's appropriate for treatment; correct?

A. Yes.

Q. Did anyone from Ethicon and Johnson & Johnson, ever try to get you to use the Prolift+M product?

A. No, it was never offered to us, nor did we ever inquire about it.

Q. Do you have any kind of understanding of what the Prolift+M product is made from or how it's different from the Prolift product?

A. I do.

Q. What's your understanding of how it's different than the Prolift product?

A. The M creates an opportunity for mesh to potentially be absorbable. So it's -- it uses an absorbable suture in it with the Monocryl. So you have prolene interweaved with Monocryl.

So the thought is that, if you have a part -- it creates a partially absorbable mesh. The thought is maybe this will improve symptomatic -- symptoms for the patient and also improve their anatomic location. It was a thought, but in looking

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at the literature, differences between the two are very minimal in terms of prolapse support and, in terms of complications, certainly are still similar issues with erosions and extrusions and all of the other potential issues from pelvic floor surgery.

Q. Are you familiar with the Prosima product?

A. I have heard of it but I've not used it.

Q. Do you know what the Prosima product is made from?

A. I don't know off the top of my head, no.

Q. Do you recall if anyone from Ethicon and Johnson & Johnson ever tried to sell you the Prosima product or get that in your hospital?

A. I know that they did not, no. I would have remembered that and certainly asked about it.

Q. Do you have an understanding that the Prosima product doesn't have mesh arms like the Prolift does?

A. Like I said, I haven't used it so I don't remember the specifics of it. I'll take your word for it that it doesn't have arms.

Q. So since you're not familiar with the product, I'll take it that you don't intend to offer an opinion in this case one way or the other,

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whether the fact that the Prosima product does not have mesh arms but the Prolift product does, whether or not that's a benefit of the Prosima product?
A. I certainly can -- I've not used it personally, but I certainly can review literature and make comments on success, anatomic success and side effects, complications, erosion, extrusion, dyspareunia, things like that. I certainly can interpret that literature. But I can't say from a user perspective any differences.
Q. But you haven't done that, at least at that time, in your expert report, any kind of analysis on the Prosima product or whether a mesh product without arms is superior or not superior to a product with arms like the Prolift?
A. No, as I said, I certainly can review literature and make expert comments about it, but I can't say I've used them.
Q. My question is have you done that at this time?
A. Have I done that at the time. I may have made reference in my report to an article or two that have used that, but I would have to look specifically at that.

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Q. Do you have an opinion as you sit here today whether or not a mesh product without arms has safety and -- safety or efficacy benefits over a product with arms like the Prolift?
A. I think there are complications that can be associated with all of them, arms or no arms. There can be challenges and issues with implantation and anatomic success and postoperative pain and problems associated with all of those.
Q. But do you have any opinions of whether a product with arms is more or less likely to cause complications than a product without arms like the Prosima?
A. I can't say that at this time, no.
Q. Are you familiar with the Elevate product?
A. I've heard of it, I have not used it.
Q. Are you familiar with the fact that, unlike the Prosima, the Elevate product does not have trocar passes?
A. Yes.
Q. But you know -- and you know that it's a mesh product?
A. I do know it's a mesh product, yes.
Q. Do you have any opinions whether there is a

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safety benefit to a product like the Elevate that doesn't have trocar passes compared to a product like the Prolift that has multiple trocar passes?
A. Certainly, injuries can still happen: Bowel, bladder, nerves, other structures in the path of how you are securing this mesh, even though it doesn't have trocar passes. There certainly still can be significant complications with these as well.
Q. I understand that. But do you have an opinion as to whether or not a product like the Elevate that has zero trocar passes is more or less likely to cause complications than a product like the Prolift that does have trocar passes?
MS. ROBINSON: Object to form.
A. I mean, it's hard to say for any of these things. Even the mesh products that you spoke of. I mean, complications are in the hands of user. And if you know how to use a Prolift, you will do it well and you won't have any injuries. If you don't know how to use an Elevate or a Prosima, you will have significant complications. At the end of the day, it comes down the end user of these products. The answer is for any of these products you can have very significant injuries.

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Q. You would agree with me that if a product has no trocar passes in its design, then a person can't be injured from the trocar passes; correct?
MS. ROBINSON: Object to form. Asked and answered.
A. You can't be injured from the trocar passes, but you can be injured for how you use the setup and how you're securing this mesh and what you're securing it to.
Q. Would you agree that a product with no trocar passes has potential safety benefits over a product that has multiple trocar passes?
A. Again, it comes down to the end user. The trocar passes in the Prolift are straightforward. They can be done tactile and with the -- under vision. I have been able to do that with both, and I've never had any significant injuries.
Q. My question is, specifically, do you believe that there's a potential safety benefit to a product with zero trocar passes as opposed to a product with multiple trocar passes?
MS. ROBINSON: Object to form. Asked and answered.
A. It certainly can. Again, all of these are

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issues related to the end user. If the end user knows how to use the product, then they all should do well.
Q. Would you agree that, in general, if you're designing a product or procedure, you want to design it with as few trocar passes as possible to accomplish the intended result?
A. I don't know if the issue is with the trocar passes. I think the issue is with the end user.
(The reporter read from the record as requested.)
MS. ROBINSON: And I'm just going to note my objection. He's not been offered as a design engineer or anything like that to testify about that, and he's answered, I believe, to the best of his ability your questions.
MR. FAES: Let me ask it a different way.
Q. Doctor, do you have any opinions to a reasonable degree of medical certainty whether or not a -- whether or not it would be better to design a product with as few trocar passes as possible to achieve the intended result?
A. It may not necessarily be the trocar passes

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that are the problem in patients who have complications from surgeries like this. Again, it may relate to many other issues including the user and how they fashion the mesh and how they secure it. You know, the most common complications people have, pain, dyspareunia, erosion, extrusion, those all relate to procedural things that a surgeon is doing. The complication that you're talking about that are trocar based are extremely rare.
Q. Can you answer the question yes or no? If you can't answer the question yes or no, just tell me and I'll move on. Can you answer the question yes or no: Do you have an opinion in this case as to whether or not it would be best when designing a product like the Prolift to design it with as few trocar passes as possible to achieve the intended result?
A. No, I do not believe that the number of trocar passes relates to the success of product. It relates to the success of the end user's ability to use the product.
Q. Now, Doctor, you've been a litigation consultant for Ethicon and Johnson & Johnson since approximately 2004; is that accurate?

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A. No, the last four years or so.
Q. I'm sorry, I misspoke. Doctor, you'd agree that you've been a litigation consultant for Ethicon and Johnson & Johnson since approximately 2014; is that accurate?
A. Maybe a little before that, but yes.
Q. So perhaps in late 2013 is when you were first approached by lawyers from Ethicon and Johnson & Johnson to be a litigation consultant; right?
A. Yes.
Q. And was that first case that you were approached the Edwards case?
A. Yes.
Q. And you've essentially been a litigation consultant for Ethicon and Johnson & Johnson since that time; is that accurate?
A. Yes.
Q. I'm going to hand you what's been marked as Exhibit No. 4 to your deposition. And I'll represent to you that these are the invoices that were produced to us from attorneys from Ethicon and Johnson & Johnson regarding work you did as a litigation consultant between November of 2015 and April of 2016. If you need to take a minute to

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review that, you can do so.
But my question is: You'd agree that in a space of less than six months, between November of 2015 and April of 2016, you earned more than $45,000 for approximately 115 hours of work as a consultant for Ethicon and Johnson & Johnson?
A. I haven't summed the numbers up, but if that's what it comes out to, then that's what it is.
Q. Would you agree that that's nearly half your entire salary from the State of West Virginia in 2015?
A. It very well may be.
Q. In fact, your entire annual salary from the State of West Virginia in 2015 was $110,524.32?
A. That's correct.
Q. And that's for -- that salary of $110,000, give or take, is for working the entire year, 40 hours a week, minus vacations and holidays; right?
A. No.
Q. No? Tell me where I'm wrong.
A. Well, you have my state salary. We're paid by the university as well as by the state.
Q. I understand. And you've also earned approximately $11,500 for another case, the Oxley

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case?
A. If that's what's written there.
Q. It's not written there, I'm just asking.
A. I couldn't tell you those numbers off the top of my head. The rates and information certainly can be made available to you.
Q. If you testified that you billed approximately $11,500 to review materials and write your report in the Oxley case, would you have any reason to disagree with that?
A. I would not.
Q. Do you recall how much you billed in the -- in the Edwards case?
A. I don't know off the top of my head.
Q. Do you know approximately how much it was?
A. I don't.
Q. Now, you've also been a consultant for Medtronic. Is that accurate?
A. I used to be.
Q. You've done speaking engagements for them within the last three years, which you were paid for?
A. No.
Q. No?

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A. Not that I know of in the last three years. It probably is longer than that. Or maybe I've been to a conference as such. I think it's longer than that.
Q. You don't recall -- well, perhaps in the last four years. Does your answer change then?
A. It might.
Q. Do you recall being paid $3,000 compensation by Medtronic for a speaking engagement in October of 2013?
A. No, I don't remember the specifics of that. I used to be a proctor for sacroneural modulation, so it may have been a proctoring event where I had gone to another institution, but I don't remember the specifics of where that was.
Q. Do you have any reason to dispute whether or not you've been paid by Medtronic for a speaking event in the past?
A. Not at all, no. I don't think it was a speaking event. I think it was a proctoring event. Those speaking events have disappeared a long time ago, have dissipated a long time ago.
Q. You've also received payments in the past from Cook Incorporated; is that correct?

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A. Not to my knowledge, no.
Q. You don't ever recall receiving any payments of any kind from 2013 to the present from Cook Incorporated, which is a medical device company?
A. No, I don't remember.
MS. ROBINSON: I'm sorry, what are you saying, what's the name?
MR. FAES: Cook Incorporated.
Q. Have you ever received payments in the last four years from Olympus America?
A. Not that I remember, no.
Q. Have you ever received payments in the last four years from Astellas Pharmaceuticals?
A. Astellas.
Q. Astellas, yes, thank you.
A. Not that I recall. Speaking engagements are things that really stopped a long time ago. The way reporting is, if I had gone to a dinner or a conference and they paid for a meal for us, whatever that may be, those are now reportable so there may be events like that. I don't remember any significant sums of money from any of those companies.
Q. Didn't you testify in 2014 during the Edwards

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case that most of those events had been stopped because your university had a policy against that?
A. Well, they're stopped because the university had a policy against that, but it also stopped because the industry doesn't do those anymore. The reps don't come around. There's no industry reps that come to universities. There's no such educational forums anymore. It's a combination of both things.
Q. Do you recall when your university implemented that policy?
A. Probably about the same time as our last engagements. Maybe 2013 or so. I don't remember.
Q. Have you ever received payments from Cumberland Pharmaceuticals --
A. Not to my knowledge.
Q. -- in the last four years?
A. Not to my knowledge.
Q. Have you ever received payments from Amgen Incorporated, A-M-G-E-N?
A. Not to my knowledge, no.
Q. Have you ever received payments from Boston Scientific in the last four years?
A. Not to my knowledge, no.

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Q. Have you ever received payments -- well, back up.

You know that Boston Scientific is a manufacturer of pelvic mesh products like Ethicon and Johnson & Johnson?

A. Yes, I do.

Q. Have you ever received any payments in the last four years from GlaxoSmithKline?

A. Not that I know of. I used to be a speaker for them many years ago, but not that I remember in the last four years.

Q. What did you speak for them regarding?

A. Their medications for erectile dysfunction and overactive bladder.

Q. What's their drug for overactive bladder?

A. Overactive bladder was -- I'm trying to remember. Let's stick with erectile dysfunction. It was Levitra, was the bigger of the two agents.

Q. Have you received any payments the last four years from Intuitive Surgical?

A. I took a robotics course, and my expenses may have been paid for that, but I have not received any payments.

Q. Assuming that reimbursement for expenses is a

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payment, you would agree that you've received payments from Intuitive Surgical in the last four years?

MS. ROBINSON: Object to form.

A. No. My expenses were paid for by the university if a bill was sent on my behalf, but I never received a check from Intuitive for anything.

Q. Have you received any payments within the last four years from Lumenis, Inc.?

A. Not to my knowledge, no.

Q. Are you aware that the government actually keeps track of payments to physicians and publishes those on their website?

A. I'm sure they do.

Q. Have you ever checked that website for any of the payments that may have been made from industry to yourself?

A. There was an update on the Sunshine Act that happened a few years ago. I went back and checked that last time it was updated and didn't see anything of note other than some meals, and I think there was something from Medtronic.

Q. So if the government website showed that in 2013 you received nine payments from Medtronic USA

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Inc. for a total amount of $4,948.12, do you believe that that information is inaccurate?

A. I believe that information is accurate.

Q. So does that change your answer as to whether or not you've received payments from Medtronic in the last four years?

A. That I -- I've received payments from them, yes. But nine payments that sum to $4,000 is not any significant amount of money.

Q. So $5,000 isn't a significant amount of money to you?

A. Over nine payments?

Q. That's correct.

A. No, it's not a significant amount of money.

Q. If the government's website showed, in 2014, that you received 25 payments for a total amount of $12,503.88, would you have any reason to disagree with that?

A. I would not.

Q. Is $12,000 -- $12,500 over 25 payments a significant amount of money to you or not?

A. No. That's $12,000 divided by 25, so no, it's not significant.

Q. Besides Ethicon and Johnson & Johnson, what

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other pharmaceutical or drug companies have you done consulting work with or for over the last ten years?

A. Over the last ten years? I've worked with Pfizer. I worked with Ortho-McNeil. I'm not sure of any other ones, it's been so long.

Q. And Ortho-McNeil is actually a Johnson & Johnson company just like Ethicon; is that accurate?

A. They may be, but that's many, many years ago.

Q. How many years ago was it when you last consulted for Ortho-McNeil?

A. Maybe 2005 or so. It's been a long time.

Q. Do you recall what kind of consulting work you did for them in 2005?

A. I was a speaker for the overactive bladder medications.

Q. Do you recall how many speaking events you did for Ortho-McNeil or Johnson & Johnson company for their overactive bladder medication?

MS. ROBINSON: Object to form.

A. Over when? Over what time period?

Q. Over your entire period of consulting with them?

A. I couldn't tell you how many. It goes back 15 years.

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Q. Is it more than ten?
A. It's more than ten.
Q. More than 20?
A. It might be. I don't remember. It's been a long time.
Q. Do you recall what you were paid for each of those speaking engagements?
A. Each was -- at that time maybe $500.
Q. For how long of an engagement?
A. It depends. An hour or so, plus travel.
Q. What kind of consulting work did you do for Pfizer?
A. I was a speaker for their overactive bladder and erectile dysfunction medicines.
Q. So was it a competing overactive bladder medication to Ortho-McNeil's overactive bladder medications?
A. Yes.
Q. Did you do consulting regarding both overactive bladder medicines at the same time?
A. Yes.
Q. Did you see that as any kind of potential conflict of interest?
A. No.

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Q. Do you know if Ortho-McNeil and Pfizer were aware that you were consulting for both of their overactive bladder medications at the same time?
A. Yes, I'm sure they were.
Q. Why are you sure they were?
A. I'm the only female pelvic specialist in the State of West Virginia. I'm the only board certified urologist who deals with voiding and sexual dysfunction, which makes me the authority in the state to teach at all levels; to physicians, to nurses, nurse practitioners in a variety of different forums. So industry would sponsor my ability to speak throughout the State of West Virginia, to educate doctors at roundtable forums, at Grand Rounds, CME events throughout the state, beginning with my arrival in 2001.
MS. ROBINSON: When you get a second, can we take a bathroom break.
MR. FAES: Right now is perfect.
(A brief recess was taken from 3:13 p.m. to 3:15 p.m.)
BY MR. FAES:
Q. Doctor, we're back on the record after a short break. Are you ready to proceed?

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A. Yes.
Q. Before we went off the record, we were discussing various pharmaceutical and medical device companies that you've done consulting work with over the last ten years. Other than Pfizer and Ortho-McNeil, are there any other companies you can think of?
A. I cannot.
Q. Are there any companies that you've -- pharmaceutical or medical device companies that you've received grants from in the last ten years?
A. No.
Q. And I know you've been asked this before, but I just need to ask it again to see if the answer's changed. Are you currently doing any litigation consulting work for anyone other than Ethicon and Johnson & Johnson?
A. I am not.
Q. Not doing any consulting work for Boston Scientific?
A. No.
Q. Or American Medical Systems?
A. No.
Q. Or C.R. Bard?

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A. Nobody else.
Q. Okay. Doctor, I'm going to hand you what's been marked as Exhibit No. 8 to your deposition.
And this is a document that's been produced to us by Ethicon and Johnson & Johnson.
(Dr. Zaslau Deposition Exhibit No. 8 was marked for identification.)
Q. And you can see on the first page it's a field visit letter from ESC sales representative; do you see that?
A. Yes.
Q. And it's dated September 25th to 26th, 2013. Do you see that?
A. Yes.
Q. It says the sales rep name is Kristen Brikis. Do you see that?
A. I do.
Q. Do you recognize that name?
A. Not at all.
Q. So you don't -- never talked to Kristen Brikis, a sales representative from Ethicon and Johnson & Johnson, to your knowledge?
A. Never seen her.
Q. If you can turn to -- it says page 3 of 8

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down here (indicating). And I want to ask you specifically about the middle of the page where it says -- starts with WVU, dash, and it states, "After meeting with Dr. Zaslau, Board Certified Professor and Chief of the Urology Residency Program, I wanted to see if he was performing less TVT Sling procedures since the mesh lawsuits. Dr. Zaslau confirmed he is a committed" Ethicon -- sorry -- "Gynecare/Ethicon TVT user. He also mentioned that the reason for the decline in TVT classic sling (-30K) is due to Dr. Shapiro leaving WVU Hospital."

Do you see that?

A. Yes.

Q. And it also says, "Dr. Zaslau is interested in working with Ethicon-he would also like any education assistance with the residents."

Do you see that?

A. For the residents, yes.

Q. Does this document refresh your memory at all about having a discussion with Ms. Brikis?

A. No.

Q. Regarding these issues?

A. No.

Q. Do you recall having any kind of conversation

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with a sales representative from Ethicon and Johnson & Johnson around this time?

A. We never saw them after say 2009 or 2010. So if someone had shown up, maybe they had shown up on an individual day and said, Oh, I'm the rep. Certainly, I don't know who this is person is. Second of all, Dr. Shapiro never left WVU hospital so I don't know where that comes from because he's still here. Maybe the person is confused with someone else.

Q. Do you recall expressing an interest to a sales representative at Ethicon and Johnson & Johnson in this time frame, in September of 2013, that your -- that you're interested in working with Ethicon?

A. I'm sure if there was a rep who was there at that time, who I don't remember who they were -- I'm sure that I would say that we would like any education assistance for the residents. Meaning, is there any academic programs that they have coming up, any textbooks that are available for residents in learning surgeries of the pelvic floor, any grants that were available for them. We look for that for all industry then we can support our

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resident education.

Q. And this was actually about the time that you were approached by Ethicon and Johnson & Johnson to work with them as a litigation consultant; is that accurate?

A. It may have been around that time.

Q. Well, you stated that you first started working on the Edwards case in approximately late 2013, and this is late 2013; correct?

A. I thought I was asked in about 2012 or so to begin doing things, and I was contacted by attorneys from -- I'm trying to remember what --

Q. Butler Snow, perhaps?

A. From Butler Snow in about 2012 or so. And then there was a bit of ramp-up time before any kind of involvement in anything.

Q. So you believe that you were actually contacted in approximately 2012 for the first time regarding being a litigation consultant for Ethicon and Johnson & Johnson?

A. Somewhere around there. But it took -- definitely there was some ramp-up time and effort.

Q. Do you recall who your first contact was with --

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A. Yes.

Q. -- attorneys for?

A. Yes, Brian Jackson.

Q. And when was the first time you submitted a bill for consulting work for Ethicon and Johnson & Johnson?

A. I don't remember. I would have to look back. There were a lot of discussions for a period of time and then there was a lot of downtime. There was more discussions and more downtime and then assignments.

Q. Do you believe that this record is inaccurate, that you would have expressed interest in working with Ethicon in September of 2013?

A. No, I think this is very accurate. I'm always interested in working with all industries that will benefit the education of our residents. And to this day, any rep I would ever see would always ask for educational assistance for residents.

Q. I'm going to hand you what's been marked as Exhibit No. 9 to your deposition.

(Dr. Zaslau Deposition Exhibit No. 9 was marked for identification.)

Q. And this is an e-mail produced from Ethicon

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and Johnson & Johnson files dated September 19th of 2003. Do you see that?
A. Yes.
Q. And you see that it says the subject is, "Important AUGS Leads." And you can see that your name and address is the second name down on the first page?
A. I do.
Q. And if you turn to the following page, it indicates that, "These clinicians expressed strong interest in evaluating the MoniTorr. Please follow up with them and let them know if you need assistance."
Do you see that?
A. I do.
Q. Do you recall going to an AUGS convention in 2003 and expressing interest in the MoniTorr product to representatives from Ethicon and Johnson & Johnson?
A. I probably did. But I've had interest in that product since it was released even before going to that meeting.
Q. Would you agree that one of the purposes of the AUGS conventions is for manufacturers like

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Ethicon and Johnson & Johnson to showcase their new products?
MS. ROBINSON: Object to form.
A. They certainly could be, yeah.
Q. And did you ultimately end up evaluating the MoniTorr product?
MS. ROBINSON: Object to form.
A. Did I evaluate it? It's something we considered purchasing but never did.
Q. Why did you not -- why did you end up not purchasing the MoniTorr after evaluating it?
A. You're asking me something that's not relevant to any of this discussion, but I'll take the time to explain it to you.
So the MoniTorr is a urodynamic system used to evaluate voiding dysfunction in patients. It was a very simple office-based procedure that would allow patients to have bladder systematic studies and voiding studies over a short period of time in an office visit without having to go to a hospital. And I thought this would be an interesting device for our office and for convenience of patients and ease of performing the procedure. And after researching it, it didn't

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catch my eye to meet the needs that I wanted from it. So I didn't go any further.
Q. I'll hand you what's been marked as Exhibit No. 10 to your deposition.
(Dr. Zaslau Deposition Exhibit No. 10 was marked for identification.)
Q. And this is an e-mail string dated January 30th, 2012. Do you see that? It's on the very first page.
A. Yes.
Q. You've already flipped to the second page, and I've taken the liberty of highlighting your e-mail address. At least I believe that's your e-mail address. That is your e-mail address, SZaslau@hsc.wvu.edu?
A. That's correct.
Q. This is an e-mail that you would have received in January of 2012; is that accurate?
MS. ROBINSON: I just object to form. You know, if he can take a minute to look at this document.
MR. FAES: Sure.
MS. ROBINSON: I can't even count how many e-mail addresses.

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MR. FAES: Like I said, I highlighted his e-mail for him so he doesn't have to go through it all.
Q. The question pending is: This is an e-mail that you would have received on January 30th of 2012; is that accurate?
A. Well, it's an e-mail I could have received. Some of our e-mails are quarantined and put in a clutter or a junk folder. So it may have been something that I would have to search for. But certainly, in looking at it, it's not something that I'm struck by to attend or to be a part of.
Q. So your answer is you don't know one way or the other if you actually received this e-mail on January 30th of 2012 or not?
A. No, I don't know. I don't have independent recollection of it. Nor, as I read it, would I jump to attend it.
Q. Okay. Well, if you turn to the following page, it states that in past years, in the second paragraph, that they've conducted an annual summit meeting around the February/March time frame where they discussed topics related to the treatment of these critical conditions, meaning above stress

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urinary incontinence and pelvic organ prolapse. In 2012, we will not continue to facilitate these types of important discussions in a variety of formats but will not be holding a one-time formal summit meeting. Do you see that?

MS. ROBINSON: Are you asking him if he sees it?

MR. FAES: First, I'm asking him if he sees that.

A. I see what you said. You said "we will not." It says we will continue to facilitate these types of important discussions but will not be holding a one-time formal meeting.

Q. Okay. Thank you. Do you remember being informed by Ethicon and Johnson & Johnson in January of 2012 that they would not be having a formal meeting regarding SUI and POP as they had in years past?

A. No, nor do I have any recollection of this message at all.

Q. But we can see on the second page that, apparently, Ethicon and Johnson & Johnson did have your WVU e-mail address?

A. Yes, it appears that they did.

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Q. Do you regularly get e-mails from Ethicon and Johnson & Johnson?

A. Not now. In the past maybe. But not commonly.

Q. How often did you get e-mails like this in the past?

MS. ROBINSON: Object to form. It mischaracterizes his testimony. He doesn't know if he got this or not.

A. Not often, if at all.

Q. Do you still have any e-mails from Ethicon and Johnson & Johnson in your possession?

A. No.

MS. ROBINSON: Object to form.

Q. And you've looked for them?

A. No.

Q. If I can have you look back at Exhibit No. 1 which is the notice of your deposition.

MR. FAES: I think I gave him my copy again. I did.

Q. I'm going to have you look at, specifically, Paragraph 11 on Exhibit No. 1. And one of the items that we've requested is all correspondence, memoranda, e-mails or other documents reflecting

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communications including written, electronic and/or oral with any employees or defendants related to any female pelvic mesh product sold by Ethicon Inc. for the treatment of stress urinary incontinence or pelvic organ prolapse. Do you see that?

A. I do.

Q. Did you make any attempt to comply with the federal rules and see if you had any documents responsive to Paragraph No. 12 in your possession?

A. No, because an e-mail like this, I would delete it at the time that I got it because it's not pertinent to me. And if there were anything that was pertinent, I would save it, but I never had any e-mails that had any pertinence whatsoever over the years.

Q. To be clear, you haven't actually gone and looked for any documents responsive to item 12 in our request?

A. I don't have any. I don't have any.

Q. Have you looked?

A. I look as I get e-mail. If it's there -- if I received an e-mail like this today -- let's pretend this is today. I would look at an e-mail like this, and I would delete it, so I don't have

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any.

And to further that, e-mail in my junk cabinet as I go through it, it gets deleted. E-mail in my clutter file, if something like this were in there, it would also get deleted, so I wouldn't have any.

Q. So since you've been a litigation consultant for Ethicon and Johnson & Johnson, you regularly delete e-mails received from them?

A. E-mails like this inviting me to a forum, yes, but otherwise, no, I don't get any e-mails from Ethicon.

Q. Approximately how many e-mails like that would you say that you receive on an average month?

MS. ROBINSON: I'm going to object to form and also want to note for the record, my guess is that we've filed an objection to his notice of deposition.

MR. FAES: So noted.

MS. ROBINSON: I just want that noted.

MR. FAES: Okay. Can you read back the pending question.

(The reporter read from the record as requested.)

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A. Again, we're referring to this particular e-mail, this mass e-mail sent to a variety of people from Ethicon; right?
Q. Yes.
A. The answer is, maybe once or twice a year, and no, I don't take them seriously.
Q. What about other e-mails that aren't, as you characterize, mass e-mails; how many other Ethicon e-mails that aren't mass e-mails would you say that you receive on an average month, excluding, of course, any e-mails from counsel?
A. None.
Q. I'm going to hand you what's been marked as Exhibit No. 11 to your deposition.
(Dr. Zaslau Deposition Exhibit No. 11 was marked for identification.)
Q. Take a minute to go ahead and review that.
(Witness reviews document.)
Q. And I specifically want to ask you, starting on the second page where it states, "Here are the Team Keystone submissions for the TVT World registry. These submissions have been well thought out. I believe Halina Zycznski has already been approached by David Robinson. We should include the

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other two at Magee for sure, Moalli & Sagan. Please let us know if you need any additional docs or information."
You see that at the top of the second page?
A. I do.
Q. Then if you go down, it says, "Ron Rink," and then there's a number of physician names, and on the second page you're No. 5.
A. Okay.
Q. Dr. Stanley Zaslau. Do you see that?
A. Yes, I do.
Q. Do you recall ever being approached by Ethicon and Johnson & Johnson to participate in the TVT world register?
A. No.
Q. Did you participate -- did you ever participate in any way in the TVT world register?
A. No.
Q. Do you know who Ron Rink is?
A. I do know who Ron Rink is. Ron Rink was our last known TVT rep -- our last known Ethicon rep to step foot in WVU, that was about 2008, 2009, I think, is when he -- he was not part -- either not

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part of the company or the reps weren't servicing us. He's the last known name that I know as an industry representative.
Q. Did you ever have any personal meetings or contacts with Ron Rink?
A. He would come for cases occasionally. But really he was just there to make sure supplies were available.
Q. When you say he came for cases, what do you mean by that? That he actually sat in on surgeries?
A. He would observe the cases that we're doing. If we had a few Prolifts or TVT obturator or whatever cases that were going on, he would come and be a part and observe.
Q. Did he ever provide you with any information or materials, such as patient brochures or doctor brochures talking about the products?
A. I've seen patient brochures over the years. We've had patient brochures over the years, and it's easier to sit with a patient and describe things than to give them a brochure, so we kind of stopped that over time.
Q. What patient brochures have you used from Ethicon and Johnson & Johnson in the past?

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A. It's been many years. I -- I couldn't tell you the specific ones that we've had. The initial Prolift patient brochure, I'm sure we had. Then we didn't have any more so it was easier to just talk with patients than sit and read them a brochure.
Q. Did Ron Rink ever e-mail you materials or e-mail you information or e-mail you about cases?
A. No.
Q. You don't recall ever receiving any kind of e-mails of any kind from Ron Rink over the six years of his employment with Ethicon and Johnson & Johnson?
A. I don't remember, no.
Q. Is it possible that he did e-mail you and you just don't remember one way or the other?
A. It's possible he did and I read it and deleted it. But again, nothing of -- things that would come from Ron Rink would be things he would have sent to the office. Brochures or things he may hand me about a product. Okay, here's a brochure, if he's in the OR. But nothing by e-mail that I recall.
Q. Do you know that we've been told by Ethicon and Johnson & Johnson that all of Ron Rink's e-mails

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and materials and items he had when he left Ethicon and Johnson & Johnson have been lost by the company?
MS. ROBINSON: Object to form.
A. Yeah, like I said, I haven't seen Ron Rink since 2008 or 2009, so I couldn't comment.
Q. Do you know when the Gynemesh PS product was first available for sale in the United States?
A. It was in the early 2000s sometime.
Q. So you believe that the first time that the Gynemesh PS product was available for sale was in the early 2000s?
A. Sometime around there. I mean, certainly it was before Prolift. So Prolift is, what, 2004. So that's got to be, what, the year before, somewhere around there.
Q. And I noticed -- correct me if I'm wrong -- you haven't noted the date that the Gynemesh PS product was first made available for sale in the United States anywhere in your expert report; have you?
A. No.
Q. Did you not feel that that was an important fact to know in offering your opinions in this case regarding the Gynemesh PS?

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A. No.
Q. Do you know when the -- actually, let me clarify that. Is your answer, no, you don't think it's an important fact to know in order to issue your opinions, or yes, you think it is an important fact to know?
MS. ROBINSON: Object to form.
A. To know the date when it was first put out?
Q. Yes, when it was first available for sale in the United States.
A. I said it was in the early 2000s. I think that's specific enough.
Q. But you don't know any more specifically than that, and you don't think it's important to know?
A. No, it's in the early 2000s.
Q. Is it your opinion in this case that the Gynemesh PS product has been safe and effective for the entire time that it's been on the market in the United States?
A. It's been safe and effective, yes. It has its known complications of what you would expect for any other mesh, but better than its predecessors from the mid-1990s.
Q. So you have the opinion that its been safe

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and effective for the entire time that it's been on the market in the United States, but you don't know specifically what that time period is?
A. I said the time period is the early 2000s. You want me to pin it down to an exact year?
Q. Do you know the exact year?
A. Yeah, the exact year is 2002.
Q. Okay.
A. But that's the early 2000s.
Q. Do you know what the Prolene Soft product is?
A. It was a variation of prolene mesh with different weight and some different characteristics to it.
Q. Do you know what the differences are between Prolene Soft mesh and the Gynemesh PS?
A. I'd have to look specifically at the details between the two, in terms of the dynamics.
Q. Do you know when the Prolift product was first made available for sale in the United States?
A. About 2004. 2005.
Q. Do you know when the Prolift product was first legally available for sale in the United States?
MS. ROBINSON: Object to form.

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A. What do you mean by "legally available"?
Q. Well, do you know when it was cleared for use in the United States?
MS. ROBINSON: Object to form.
A. You mean cleared by the FDA?
Q. Yes.
A. 2008.
Q. So you know that it was being sold by Ethicon and Johnson & Johnson in the United States before it actually had FDA clearance; is that accurate?
MS. ROBINSON: Object to form.
A. What was?
Q. The Prolift.
A. Well, the Prolift is the mesh, so the mesh was approved in 2002. The trocars were engineered products that are not relevant to prolene mesh, because they're not -- they're not housed within the body. They're just the vehicles to place the mesh.
So the mesh is the only product that stays in the body at the end of the day. So 2004, that mesh was appropriate to be implanted in patients. It's just the vehicle for it that got approved three years later.
Q. But you know that the Prolift device as an

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entire kit was being sold by Ethicon and Johnson & Johnson in 2004, 2005, 2006 and 2007, and did not have FDA clearance at that time?

MS. ROBINSON: Object to form.

A. You mean -- again, the mesh was. It's the simple --

Q. I'm not asking about the mesh. I'm asking about the Prolift kit.

A. Yes, I do know that.

Q. When you were using -- let me back up. Would you, as a physician, knowingly use a medical device that you knew had not been cleared by the FDA?

A. The device in my hands is the mesh. The mesh was cleared by the FDA. The matter in which --

Q. That's not my question, respectfully, Doctor.

A. All right. I'm respectfully answering your question.

Q. I'm not asking about the Prolift specifically. I'm asking about medical devices in general. My question --

A. What is your question?

Q. My question is, would you --

MS. ROBINSON: So let me just -- you two are interrupting each other, so if you can please

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let him finish his question and then you answer and then -- so I can keep track.

Q. My question is -- to you, Doctor, is, if you knew that a medical device had not been cleared by the FDA, would you use that device?

A. It depends on the device. This is a very different situation. This is not like a penile implant that I would put in. I certainly wouldn't implant a device such as that in someone that's not FDA cleared.

This mesh is FDA cleared. The manner in which is it is placed, i.e., the trocars, was not FDA cleared until 2008. The mechanism for which it is placed is very simplistic, and it should not require any significant efforts to do, and it was extremely useful, comfortable, ergonomic and logical, based on what we've known with the old-fashioned TVT, which was a very difficult device to place; this was effortless to do without problem.

Q. Do you know how many times the FDA told Ethicon and Johnson & Johnson in writing between 2007 and May of 2008 that they may not market the Prolift device until it has clearance?

MS. ROBINSON: Object to form.

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A. Do I know how many e-mails have been sent?

Q. I'm not talking about e-mails. I'm asking how many times -- do you know how many times the FDA told Ethicon and Johnson & Johnson in writing that you may not market the Prolift device until you have clearance?

MS. ROBINSON: Object to form.

A. I don't know how many times, no.

Q. During the period of 2007 and 2008, when Ethicon was being told by the FDA that they may not market the device until they have clearance, is that information that you would have wanted to know when you were implanting the device at that time?

MS. ROBINSON: Object to form.

A. Say it again.

Q. If you -- well, first of all, let's back up. You were implanting the Prolift device in late 2007 and early 2008; correct?

A. Yes.

Q. Would you have wanted to know during that time period that the FDA had gone to Ethicon and Johnson & Johnson and told them multiple times in writing that they should have submitted a 510(k) on the Prolift, they didn't have clearance and that

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they shouldn't continue to sell the device until they had clearance?

MS. ROBINSON: Object to form.

A. I would be more interested to know why they would actually say such a thing for such a simplistic device. Why on earth it would need to be approved is really beyond me. It's a very simple ergonomic, easy to place trocar, easier than any of their other products, including their retropubic TVT, which, as you know, is associated with numerous injuries. I don't even understand why it needed to be FDA approved. It's a device passer.

Q. That wouldn't give you any pause at all to find out that you were putting a device in the patient that did not have FDA clearance?

A. Again, I'm not putting the device in patient. I'm putting the mesh in the patient. The passers and the trocars are discarded. It's the mechanism of delivery. It has nothing to do with the device.

Q. So you were using a kit that had mesh devices and trocars to put in your patient, even though the trocars are not staying permanently in the patient, those were part of a kit that were not FDA approved; that wouldn't give you any pause -- you might not

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say to yourself, geez, maybe I shouldn't use this until they have FDA clearance?
MS. ROBINSON: Object to form. Asked and answered.
A. I was using an FDA-approved mesh with a logical and simplistic delivery system.
Q. So you would have no problem using a kit with tools that were not FDA cleared?
A. None whatsoever.
MS. ROBINSON: Just note my objection to the form and that line of questioning.
Q. Do you know what the indications for use are for the Gynemesh PS product?
A. I know what an IFU is, yes.
Q. No, no, no. My question is: Do you know what the indications -- current indications for use are for the Gynemesh PS product?
A. You would have to show them to me so I can read them. I haven't looked at them in a while.
Q. Do you know whether or not -- as you sit here today, whether or not the Gynemesh PS mesh is indicated for transvaginal placement?
A. I'd have to look at it -- I'd have to look at it and see its most recent iteration.

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Q. So you don't know as you sit here today whether it's only indicated for abdominal placement or whether it's only indicated for transvaginal placement?
A. If you want to ask me questions about the Gynemesh IFU, just show it to me, and I can look at it.
Q. But as you sit here without -- without looking at the IFU, you don't know the answer to that question; is that accurate?
A. Gynemesh should be safe and effective for use in the pelvic floor.
Q. That's not my question. My question is: Do you know as you sit here today, or is it anywhere in your expert report, what the current indications for use are for the Gynemesh PS?
A. I don't believe it's in my expert report, no.
Q. Do you believe that's an important fact that you need to know to offer an opinion that the Gynemesh PS is safe and effective?
MS. ROBINSON: Object to form.
A. I told you before that it's safe and effective. It was approved in 2002, and it certainly could be used in the pelvic floor. Then

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you're asking me about the IFU, but you won't show it to me.
Q. I'm not asking you about necessarily the IFU specifically. I'm just asking you about the --
A. You said that before.
Q. -- indications for use are.
A. You said before the Gynemesh IFU. That's what you said.
Q. So irregardless of the Gynemesh IFU, do you know what the current indications for use are for the Gynemesh PS?
A. The Gynemesh can be used for the pelvic floor, for pelvic floor reconstruction, and it should be used on a case-by-case basis determined by the surgeon and in discussion with the patient that that's the best thing for them, that's the best option for them.
Q. Do you know whether or not it is indicated for transvaginal use?
A. I haven't seen -- again, I haven't seen the latest IFU and its indications.
Q. So when you're issuing an opinion in this case, are you -- is it your opinion that the Gynemesh PS is safe and effective for use for

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placement transvaginally or abdominally or both?
A. I've not used it transabdominally. I've used the Boston mesh, and it's been fine for that. I suppose it could be used as well. It's macropore and monofilament, so it certainly would suffice for that. It certainly, based on its characteristics, should be safe for the pelvic floor, as well, even as of today. Again, after a careful discussion with -- with the patient and the then physician.
Q. Have you ever used a surgical mesh for an indication that it -- strike that.
Have you ever used a surgical mesh for an application that it's not indicated for?
A. No.
Q. You'd agree that if a person used a surgical mesh for an application it's not indicated for, that would be considered an off-label use of the product?
A. If that's how it's labeled, then, yes, it would be off-label.
Q. And as a physician, have you ever used a medical device off-label?
A. No.
Q. An off-label use?
A. No. Strike that.

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Yeah, I have done neuromodulation procedures that were meant to be unilateral. I've done them bilateral for attempted greater efficacy.
Q. Have you ever used -- have you ever prescribed a drug for an off-label use?
A. Yes.
Q. Would you agree that, generally, before you attempt to use a drug for an off-label use, you would want to attempt to use other -- other drugs, if they're available, to see if those worked first before you go to an off-label drug?
A. Depends what the indication is. Depends what the setting is. I'll give you an example. You have a female with sexual dysfunction, Viagra is not FDA approved for females, but females have sexual dysfunction and have shown improvement with that medication, even though it's indicated for males.
So intuitively, and based on the problem, one could suggest that it may be efficacious and you would use that based on your skills and training.
Q. Are you aware that the Gynemesh PS is sometimes used for physicians -- by physicians for the treatment of stress urinary incontinence?

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A. It can be, yeah.
Q. Are you offering an opinion in this case that the Gynemesh PS, if used as a treatment for stress urinary incontinence, is safe and effective?
A. We're using it in the setting of having to create a way of passing it under the urethra, so not using it in its traditional obturator fashion as part of a TVT-O or a TVT.
So if it meant fashioning the Gynemesh into that form, then that's at the surgeon's discretion of how they want to do that. But as it is on the basis of a kit, the kit, then certainly it would be safe.
Q. So the answer to my question is, yes, your opinion is that Gynemesh PS used for the treatment of stress urinary incontinence in a sling would be safe and effective?
A. It would.
Q. Have you done any kind of formal analysis to reach that conclusion with regard to the stress urinary incontinence?
A. Yeah, for suburethral slings. All macropore monofilament meshes, at least the ones that are available now, should be safe and effective.

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Q. Do you believe that implanting a Prolift device today would be within the standard of care?
A. It would. It would certainly depend on, again, the patient, the physician, the degree of prolapse, the compartment involved. It certainly could be -- could be very efficacious today in the right patient.
Q. Do you believe that implanting the Gynemesh PS transvaginally today is within the standard of care?
A. As a stand-alone piece of mesh with trocars and such created by a physician or anchoring, as such, it could be.
Q. But you don't know as you sit here today whether or not the -- implanting the Gynemesh PS transvaginally is indicated or not?
A. I mean, I don't do it. I would like to do it based on a kit. But the physician certainly could. If they wanted additional anterior support.
Q. In fact, you've never done it; right?
A. I have not.
Q. Do you agree with the FDA's viewpoint that there's a need for more rigorous studies regarding the safety and efficacy of mesh kits?

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A. Certainly study is always warranted for any device and to look at the long-term follow-up.
Q. Do you believe that there are adequate studies to support the safety and efficacy of a Prolift device?
A. There's lots of studies done over the years with long-term data, yes.
Q. So you believe that there's an adequate amount of long-term data with regard to the Prolift device to support its safety and efficacy?
A. Well, it depends where we're going to define "long-term." We have seven-year data for Prolift. We have five-year data for Prolift that's been published. It would be nice have to 10-year data, 15-year data. Certainly that could come with time, nice to have. But we have long-term data that showed that when it was out, while it was out it was effective at reducing prolapse and symptoms.
Q. So my question is -- is pretty simple: Do you believe that there's adequate long-term safety data on the Prolift to support its use?
A. Yes.
Q. And if the FDA's viewpoint was that there isn't enough, you would disagree with that

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viewpoint?
A. I think the FDA has acknowledged very clearly that there needs to be more data, and they recognize that the data that they've looked at, that there needs to be more of. It would be nice if there were randomized control trials but there're not. Many of these are treatment groups only followed for a long period of time. They've also acknowledged that this is hard to do; it's hard to get long-term data.
Q. Have you ever seen the -- strike that.
Have you ever seen the 522 order that was issued by the FDA with regard to the Prolift device?
A. I'm sure I have, but if you want to question me on it, I would like you to show it to me.
Q. Do you know what Ethicon did in response to the 522 order on the Prolift device?
A. Again, if you would like to question me about it, can you show me the documents.
Q. I'm just asking as you sit here today, do you know what Ethicon did in response to the 522 order on the Prolift device?
A. Well, the 522 order was about what time period?

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Q. 2012.
A. 2012, right. Okay. Do you remember what time period it was in 2012? It was about February, March. That's about five or six-page document of really very interesting questions. Break down your data further, by compartment, anterior, posterior; breakdown on your follow-up of mesh complications. Really very pretty straightforward material. But also asked at the same time for more significant data, over really what would have taken a very long time to do. They wanted follow-up over years of activity.
The response was four months later, about the summer of 2012, that they sent a letter to J&J and said, we would like to stop marketing this product right now. So a four-month time period from March until the summer. Get all this data, get all this information. And then the next response from the FDA was, no, shut it off.
Q. So you believe that the Prolift device was removed from the market at the FDA's request?
A. No. I think it was Johnson & Johnson looking and saying, look at all this data that we have to wire. I mean, it's really kind of crazy, the level

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of what they wanted. I'm sorry, it was April. Okay? So you know, you didn't specify.
How many pages is this large document? Six, seven pages. You know, we want safety and effectiveness at 6, 12, 18, 24, and 36 months, and the data that you're showing me only has 12 months. I mean, there's no way that they can give data out for what was wanted at the very little amount of times that was given.
Your study plan lacks study milestones and timeline elements. Looking at this and saying, okay, this April of 2012. Then they turn around July 9th of 2012, said, well, we're suspending your study. There's no way, even if they wanted to, that they could adequately satisfy every effort that the FDA wanted in four months.
Q. Do you know whether or not there were other companies that were able to satisfy the FDA's requirements with regard to their mesh kits?
A. I would say very few because there was a mass exodus from the marketplace at that time because of the cost to do this. Certainly this is a lot of cost to do this work. It would be very significant to do and certainly not be able to be done in a

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four-month time period.
Q. What is your understanding of why the Prolift was removed from the market?
A. I think it was a financial decision. Was it generating -- I don't know this. This is just opinion. Was it generating as much for Ethicon as they wanted it to? Was it profitable to go forward, or was this something that, given the climate at the time, wasn't worth proceeding forward with. And they just retreated. I don't know. This is my opinion.
Q. Do you know what the 522 order that was issued by the FDA said with regard to the Gynemesh PS?
A. I don't.
Q. Do you know what Ethicon and Johnson & Johnson did in response to the 522 order for the Gynemesh PS?
A. I don't.
Q. Do you have an opinion -- do you intend to offer an opinion in this case on whether or not the Prosima device has a different safety profile than the Gynemesh PS device because of the amount of mesh contained in that device?

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A. Certainly that there is going to be similar safety issues for any of these mesh products with infection, erosion, pain, problems, each to varying degrees, just on the basis of the material and the defect.
Q. Do you know whether or not the Gynemesh PS product is still on the market today?
A. I don't.
Q. So would you agree that from the time that Ethicon started legally marketing the Prolift device to the time they removed it from the market was approximately five years?
A. So 2000 --
MS. ROBINSON: Object to form.
A. Well, from the time I began using it, 2005 to 2009. Is that the five-year period?
Q. But Ethicon wasn't legally marketing the Prolift kit until 2008; correct?
MS. ROBINSON: Object to form.
A. Well, as far as the, quote, kit, no, not until 2008. But as far as, you know, I couldn't have used it after 2009. I didn't have access to it. 2004 to 2009, I had five years to use the product.

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Q. Do you know what the shelf life of the Prolift product is?
A. No, I know that there's an expiration date on every box, and once the expiration date has passed, we don't use those products.
Q. Would it -- do you believe that would be within the standard of care to implant a Prolift product that's expired?
A. I haven't done it.
Q. That's not my question. My question was: Do you believe it would be within the standard of care to implant an expired Prolift product?
A. Well, the standard of care is not to harm the patient at the end of the day. If the physician looked at the product, didn't find any obvious defects in it before implanting it and made that decision to do so, that would be fine.
Now, if the product is six years old, which it shouldn't be because we go through the shelves very regularly -- I can't imagine a six-year-old product being implanted; a few weeks, month, months -- that's going to be up to the individual physician. You inspect your products before you ever implant them anyway.

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Q. Do you know why a Prolift product has an expiration date or a shelf life?
A. No.
Q. So not knowing whether or not the purpose is of the shelf life or expiration date, do you know if a physician inspecting the product would be able to detect visually any defects in the product if it's past its expiration date?
A. Sure. You should be able to look at it and see, does it look to be its appropriate shape or form, does it look to be woven appropriately. And certainly, you can look at it very easily and see if it has any gross deformity to it.
Q. But you don't know -- do you know whether or not one of the reasons for an expiration date on a polypropylene plastic mesh like Prolift is that it can -- it's physical properties can change over time?
MS. ROBINSON: Object to form.
A. You can see its physical properties. That's why you look at it. They're visible.
Q. So you don't believe that there could be physical properties -- changes to the physical properties of the mesh that occur after the

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expiration date that can't be seen with the human eye? That it could only be seen through more rigorous testing?
A. It's certainly possible if you can look at an expired product under a microscope and might find differences in them. As you said, physical properties, meaning properties that can you see, gross properties, you can look at it and see if it looks to be normal. Or to be the way you would expect it if you're going to implant it.
Q. Would you agree that polypropylene, like any plastic, if it's stored for a long period of time, the physical properties of it can change, meaning the tactile properties; it might change to the touch?
MS. ROBINSON: Object to form.
A. We said before that the products are not kept on the shelf for years. Okay? When we're talking about beyond an expiration date, I'm talking to you about months. Because we would take any product like that and return it if it's been past its expiration date significantly. So we're really not in a situation where we're ever going to implant an expired product.

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Q. Do you know whether or not Ethicon was accepting returns of the Prolift product after it was removed from market?
A. I don't know whether they were accepting them or not, but I know that when -- we may have had two on the shelf or so, and we sent them back. I don't know what happened to them, but we sent them back.
Q. Would you agree it would be a reasonable thing to do for a company to accept returns of a medical device that they decided to no longer market and support with training?
MS. ROBINSON: Object to form.
A. Yeah, I don't -- that's up to their policies. Those aren't my policies.
Q. But you as a physician, would you expect that to be a reasonable thing for a medical device company to do, to take the product back if they were no longer going to support it or sell it?
MS. ROBINSON: Object to form.
A. That's up to -- that's up to the manufacturer. That's up to them. That's their policies.
Q. So you --
A. No, I broke my Fitbit watch. I can't get a

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new one and I asked, can I get one since the band broke and they said, no, it's been a year and you'll have to buy a whole new watch. And we're not giving you a discount for it. That's their policy. It would be nice if they would give it to me, discount or something, I'm a customer, but that's up to the company.
Q. But your watch isn't intended for permanent implantation to the human body; right?
A. Right. But it's permanently implanted on my arm. And these are products that have not been used.
Q. And your Fitbit doesn't require specialized training in order to implant; correct?
A. Well, it does, it requires specialized charging each night to work.
MS. ROBINSON: And specialized walking.
Q. You had training on how to charge your Fitbit watch?
MS. ROBINSON: You have to have training on how to get those 10,000 steps a day.
Q. So you know at least for the Prolift product, because you have some of the documents in front of you, that Ethicon tried to convince the FDA to

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accept studies they had already done on the Prolift instead of having to do additional studies; correct?
MS. ROBINSON: Object to form.
A. I mean, certainly the ones that they submitted to them were studies that had follow-up, were good quality studies, but the FDA wanted additional materials. That was their impression.
Q. Right. So the FDA essentially said, you don't have enough studies or clinical data on the Prolift at this time, we want more; right?
A. They wanted more information, yes.
Q. And you disagree with the FDA's decision on that?
A. I think there's a lot of good data that they're suggesting the long-term follow-up, a seven-year follow-up, a four-and-a-half-year follow-up, studies with showing significant improvement in the anterior compartment, the Schimpf study, looking at a variety of different products for prolapse, low dyspareunia rates, you know; I thought there was a lot of good data there, from a lot of different studies, including randomized trials.
Now, did they have five, six,

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seven-year follow-up on these randomized trials. No, they were shorter. They were one or two years. If the FDA wants more data, you have to honor their wishes and give them more data. There's a lot of good data for Prolift.
Q. Just to be clear, you disagreed with the FDA that there was more data needed on the Prolift before selling the device?
A. Yeah, I did, I did.
Q. Do you believe it would be a reasonable decision for a doctor to stop using the Prolift device following the July 2011 FDA warning?
A. If they didn't understand it, I would expect them to stop. But if they understood it, I'd expect they would keep going.
Q. So you believed that the only type of doctor that would stop using it, stop using the Prolift after the July 2000 FDA warning, is a physician that didn't understand the notice?
A. Right, they didn't understand the FDA -- they didn't understand the FDA document in 2011.
Q. Do you agree that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare?

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A. No, they're not rare.
Q. So you agree with that statement or you disagree?
A. Well, when I say "rare," I'm talking about less than 2 percent. Okay? So when you look at the data for pelvic mesh complications, that complication rate can be between zero percent and some studies have quoted much higher percentages. So it depends on how you define "rare." A rare disease may happen in 1 percent of people. If you sum together all potential complications a person could have, it would be more than 1 percent.
Q. Well, are you aware that the FDA public health notice specifically states that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare?
A. Yes.
Q. Do you agree with that statement?
A. Yes, I do.
Q. Do you disagree there is no evidence that transvaginal repair with mesh provides any added benefit compared with traditional surgery with mesh? -- without mesh. Strike that. I need to start

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over because I just butchered that terribly.
Do you disagree that there is no evidence that transvaginal mesh repair with mesh provides any additional benefit compared to traditional surgery without mesh?
A. Mesh does provide an added benefit, yes.
Q. So you disagree with that statement?
A. I do. I also disagree with the other statement -- with your discussion of not rare in the context of where you're reading it from. You're reading it from, if I'm not mistaken, the 2011 statement where there's a discussion of the number of cases performed in one year. Okay? I think if -- I don't have the document in front of me, but I think there were, what, 100,000 cases in 2010. Was that the year? Okay --
Q. I don't know what you're talking about.
A. Let's go through -- we'll spend time going through the FDA discussion in detail.
Q. No, we don't need to do that, Doctor. You have answered my question.
A. I need to answer your question, so I'm going to answer -- because you're talking about a document I want in front of me, okay. And you're referring

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to it, and you're not giving it to me so I'm going to take the time to find the things that you're discussing.
Q. I'm actually not referring to any specific document, Doctor. I'm just asking questions.
A. All right. Well, I'm just trying to answer them for you.
MS. ROBINSON: So we've spent another -- about another hour on the record. Can we take a break? He can look for his FDA document, and we can just take a -- little break.
MR. FAES: Sure.
(A brief recess was taken from 4:16 p.m. to 4:31 p.m.)
BY MR. FAES:
Q. Doctor, we're back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. I just want to follow up and ask you a couple questions about your supplemental reliance list marked as Exhibit No. 4. Who prepared this list?
A. Attorneys for Ethicon.
Q. How were the materials that are on this list selected?

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A. They were selected by Ethicon. There are additions made by me based on some things I asked to include over the time. This list has grown and grown. And they maintain them. But it's a supplement. I mean, there are things in here, articles I read all the time, and there's articles that are referred to in our textbooks. You know, things that over a compendium of 15 years at WVU, things I would know and work with.
Q. Is there anything that you've asked Ethicon and Johnson & Johnson for that -- or attorneys for Ethicon and Johnson & Johnson that you were unable to get?
A. No.
Q. Do you feel like you have seen everything that you need to see in order to issue your opinions in this case regarding the Prolift and Gynemesh PS?
A. Yes.
Q. Of course, you didn't put any page numbers on this, but can you look at the -- I guess it would be the third-to-last page or second-to-last page that has writing on it. It starts with expert reports, Blaivas, Jerry?
A. Yes.

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Q. Easiest if you go from the back. I see you have some depositions listed down there, Dr. Eddie Sze on 5/13 of 2006 (sic). Do you see that?
A. Yes.
Q. How does Dr. Sze's deposition from May of 2016 support your opinions regarding the Prolift and Gynemesh PS?
A. Dr. Sze had a variety of different cases for which he was the treating physician. He was deposed in Syracuse in May in about 15 different cases. I had reviewed a variety of these and some of which I was the explanting physician of mesh.
Q. But those depositions were regarding the TVT device; right? Not the Prolift or Gynemesh PS?
A. Most likely were the TVT, but I would have to look at each individual case. Like I said, there's a large number of cases, like 15 to 20 cases he was deposed in over that period of time.
Q. Can I have you turn back one, two, three more pages to the page that starts, Company Witness Depositions. Are you there, Doctor?
A. No.
Q. Tell me when you're there.
A. Company Witness Depositions, yes.

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Q. And you see -- I see there that you reviewed some testimony of Dr. Axel Arnauld from 2013. Do you see that?
(Witness reviews document.)
A. Yes.
Q. Were you aware that Dr. Arnauld was actually deposed as well in 2012, specifically regarding the Prolift device?
A. He may have. I don't remember.
Q. Do you know if you've reviewed those depositions prior to issuing your opinions in this case?
A. No. This is a really exhaustive list of things. I haven't reviewed every single deposition testimony of every single person who is here. I glanced at parts of things. I glanced at parts of some and glanced more of others and looked at some and said I'm not going to review this any further. It's just too big a body of information.
Q. But my question is: Do you recall if you've ever actually reviewed Dr. Arnauld's testimony in 2012 regarding the Prolift device?
A. I don't remember specifically reviewing that testimony.

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Q. Do you recall if he's one of the -- whether or not he's one of the medical directors that actually worked with Ethicon and Johnson & Johnson in developing the Prolift device in France?
A. No, I don't.
Q. You think that would be important testimony to have reviewed prior to issuing your opinions in this case?
A. Not necessarily.
Q. Down further down you've got Charlotte Owens?
A. Uh-huh.
Q. And there's two depositions listed in 2013. Do you see that?
A. I do.
Q. Are you aware that Dr. Owens was actually the medical director for Ethicon and Johnson & Johnson at the time the Prolift device was launched in the United States?
A. I was not, no.
Q. Are you aware that she was actually deposed as well in 2012, specifically regarding the Prolift device?
A. No.
Q. Is that information you think might have been

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helpful to you in reaching your opinions in this case?
A. No.
Q. You don't think the testimony of Ethicon's medical director at the time the Prolift device was launched in the United States would have anything relevant to say that might affect any of your opinions in this case?
A. No.
Q. Again, Dr. David Robinson, you've got three dates listed for him. Do you remember who he is?
A. I do not, no.
Q. If he was the medical director from -- for Ethicon and Johnson & Johnson from 2005 to 2010 and was also deposed in 2012, specifically regarding the Prolift device, do you think those depositions would have anything relevant to your opinions regarding the Prolift or Gynemesh PS in this case?
A. No.
Q. Doctor, would you agree with me that you are not an expert in polymer chemistry?
A. I am not.
Q. You're not an expert in chemical engineering?
A. No.

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Q. You're not -- you don't hold yourself out to be an expert in surgical pathology?
A. I review urologic pathology for things. Pathology is a part of the American Board of Urology certifying examination, so I'm comfortable reading pathology slides and interpreting pathologic information.
Q. And you, in fact, as a matter of course, whenever you remove a foreign body from a patient, including a surgical mesh, you generally send that out for pathology; right?
A. It depends on what the foreign body is. Mesh, yes, we send our removals for pathology.
Q. So you would agree with me that you have -- of all the mesh removals that you have sent out for pathology, none have ever had any kind of chemical testing done on those samples to determine if the mesh has chemically degraded; correct?
A. No.
Q. No, I'm not correct, or yes, I'm correct?
A. You are correct in that we have not sent any of our meshes for testing for chemical degradation.
Q. Have you ever done a microscopic analysis of explanted mesh to determine whether or not the mesh

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degraded?
A. Yes.
Q. What type of microscopic analysis have you done to determine whether or not the mesh degraded?
A. Well, for the two case reports that we just wrote with eroded prolene sutures from the Burch case. These were sutures that eroded into the bladder. So when we removed them, I looked at them under the microscope to look and see what the fiber looked like. The fiber looked clean. It didn't have any obvious breaks in it. Certainly, I didn't do any staining for it.
Other than the stones that formed on it from being eroded into the bladder ten years prior, it looked and felt like a normal piece of prolene mesh -- prolene suture.
Q. But my question was, you haven't done -- you've done the -- looked at explanted prolene sutures under a microscope, but you've never done a microscopic analysis of explanted mesh to see if it chemically degraded?
A. Not for chemical degradation, no.
Q. Okay. Do you intend to offer any opinions in this case regarding patient satisfaction rates for

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the Prolift or Gynemesh PS?
A. In -- yes, you know, in review of literature, and from our own population of patients, those who we've implanted are satisfied with the procedure that was performed and none, that I know of, of my own patients have required any additional repairs, meaning any additional prolapse repairs.
Q. So do you intend to offer any opinions in this case regarding any of your own patients who have been implanted with the Prolift device?
A. Other than explaining over the series that patients have been satisfied and have not had any significant adverse events, I would be saying that.
Q. So how many patients are we talking about?
A. Of the hundred that we know of and the three mesh extrusions that I have dealt with over the years and the follow-up of those patients that we know of has been extremely satisfactory.
Q. Have you done any kind of survey regarding patient satisfaction of those patients?
A. We have not done that yet, but that is a consideration as a retrospective look, looking back ten years, where these patients are now and how they're doing.

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Q. Do you know how many of those hundred patients have been lost to follow-up?
A. I don't. I'd have to look. We've had a change in our electronic record systems, is what makes this a little more challenging. So we went from paper to dictation to all computer in 2010. So searching for some of those paper charts is a little more challenging.
Q. Do you know at what interval each of those patients have been evaluated for?
A. At this level, patients should be evaluated annually. My rule is that we'll see patients at least annually after any pelvic floor surgery. So we should have annual data for everyone.
Q. But you don't know -- do you know as you sit here today how many of those hundred patients have actually -- have actually had annual data?
A. I'd have to look specifically to do that.
Q. Do you know what the average follow-up is for those patients?
A. Meaning average time period that they've been followed?
Q. Yes.
A. The longest follow-up would be 12 years, from

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2004 to 2016. The shortest follow-up could be maybe eight years or so.
Q. But have you done any kind of formal analysis of what --
A. Not yet.
Q. Let me get out the whole question. Have you done any kind of formal analysis of what the average follow-up is for those patients?
A. I have not yet, no.
Q. What do you believe the reoperation rates are for the Prolift device?
A. That's a hard question to answer. I don't know what you mean by "reoperation."
Q. Well, what do you believe are -- strike that.
Assuming that reoperation rates means any kind of operation for mesh erosion, extrusion, exposure, or failure, what do you believe the reoperation rates are for the Prolift device?
A. Let me make sure I understand. You're saying erosion, extrusion.
Q. Exposure.
A. Exposure.
Q. Or failure of the --
A. Okay.

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Q. -- treatment, failure meaning recurrent problems. Requiring reoperation?
MS. ROBINSON: And recurrent and treated or untreated or -- securing this mesh.
A. Can I take it apart?
Q. Sure. Actually, let me withdraw that question and ask a better one.
What do you believe the erosion, exposure and extrusion rates are for the Prolift device?
A. Okay. Let's focus on -- let's define erosion and extrusion; okay? Extrusion is extrusion through the vaginal wall. Meaning seen vaginally. Erosion means that it erodes into another structure. Meaning it erodes into the urethra or into the bladder. Unfortunately, the literature uses them both the same, although really they're semantically different things. We'll say erosions and extrusions for the purposes of this deposition is being visualized through the vaginal wall. Okay?
Q. Okay.
A. So the erosion rates can range from 0 percent to as high as about 20 percent. The problem is how those are treated. In many papers, the erosions can

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be managed medically with estrogen creams. In some of the papers, 50 percent of the patients with an erosion were treated early with estrogen cream. In others, they were treated just with observation and had improvement.
In terms of procedures -- but that affects the overall erosion rate. The overall erosion rate might be as high as, in a study, 19 percent, but those that required a procedure for it was only 3 or 4 percent. So it depends on how -- how you look at what erosion means and does it mean being treated, or does it mean being treated with surgery, or does it mean simple excision in the office.
Q. So what do you believe the overall erosion rate is including exposure and extrusion, for the Prolift product for any of those things?
A. It's very hard to determine. Some of the studies they break down the patients, of 21 patients, and a patient had three different procedures. So does that mean they eroded three times, or is it a single erosion. It's very hard to determine what it truly is.
Q. So yeah, I understand that it's difficult, so

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are you going to offer an opinion on this case on what the overall erosion rate is for the Prolift product?
A. Yes, I'm going to say my opinion is that the overall erosion rate is very difficult to determine, which has been cited in the literature very clearly; that there's different ways of determining what an erosion is. Does it require surgery? Were they seen by the same physician who did the surgery and someone else postoperatively? Was the same patient counted twice if they had a recurrence, meaning that they were treated medically, and then they didn't get better and required surgically (sic), is that a separate erosion or is that the same erosion? So the reporting of it is challenging as it is.
Q. I understand, but do you intend to state an overall erosion rate or an overall erosion rate range regarding the Prolift device?
A. I will say that there is a wide range of numbers that are quoted in the literature, but when those numbers are drilled down to what is surgically significant, the erosion rate is most likely somewhere between say 3 and 8 percent.
Q. So you believe that the overall erosion rate

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for the Prolift device is between 3 and 8 percent?
A. I think it's very low. I think it's overestimated and overstated.
Q. How high would the overall erosion rate of the Prolift need to be in order for you to change your opinion that Prolift is safe and effective for the treatment of pelvic organ prolapse?
A. Say that again, how high?
Q. Yes.
A. What it needs to say that it's safe and effective?
Q. I'll restate it. How high would the overall erosion rate need to be or the overall rate range need to be in order for you to change your opinion that the Prolift device is safe and effective for the treatment of pelvic organ prolapse?
A. Well, I think it is safe and effective despite the FDA -- despite the -- Ethicon's decision to not market it anymore. I think it's safe and effective. It was safe and effective. And the data is safe and effective.
Q. That's not my question. My question is -- well, you've issued an opinion in this case that the Prolift is safe and effective for the treatment of

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pelvic organ prolapse; right?
A. Yes.
Q. And one of the measures of safety is the erosion rate; right?
A. Yes.
Q. So how high would the erosion rate need to be before you would say that's too high of an erosion rate, it's not safe and effective?
A. I can't give you a number. Because it's not based on a number. The number is factual. It's going to be based on clinical experience. It's going to be based on multiple papers suggesting the same thing, that there's a problem. It's going to be based on presentations at national meetings. It's going to be based on book chapters describing this, latest edition of Campbell's urology. I think it's going to take a body of literature, of significant, compelling literature.
Q. So if you can't give me a number, does that mean that if it was shown that the Prolift eroded in 100 percent of cases, you might still say that it's safe and effective?
A. I mean, I think that's -- that's not a very sensible question. If something eroded in a hundred

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percent of cases. You know --
Q. So you'd agree that a mesh device for pelvic organ prolapse that eroded in 100 percent of cases would not be safe and effective?
A. I certainly would have a question of why is there a hundred percent erosion rate. The first thing is why is that the case.
Q. So you wouldn't even go that far in a case where the erosion rate was 100 percent to say that device isn't safe and effective?
A. The first question is why, why is the erosion rate what it is? Why? And ascertain that scientific approach to it. Why is it?
A number is a number. It doesn't have any meaning unless it's interpreted in a context. Like I'm describing to you about erosion rates, how these numbers are extremely difficult for anyone to understand. The numbers in all these different papers. But when you break down the numbers of things that are commonly quoted, especially by Plaintiff attorneys, oh, the erosion rate is 36 percent. Yeah, but when you break down that there are 21 patients and half of them are treated medically, well, yeah, they had an erosion but it

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was treated in the office with medical therapy. So it's really not significant. So the number has to be drilled down to what does it mean.
Q. So potentially a mesh device for pelvic organ prolapse could show an erosion rate of a hundred percent and you potentially would not find that device to be defective?
MS. ROBINSON: Object to form.
A. I said to you before, the first question is why. Why is it a hundred percent. Is it the product? Is it how it's delivered? Is it the characteristics of it? Why is it? Why is the number what it is? And then from there, you can make determinations as to safety and efficacy.
Q. So are there any devices, medical devices out there that you believe are not safe and effective for their intended use?
A. Not that I work with in urology.
Q. What's an example of a medical device that you think is not safe and effective for its intended use?
A. I can't think of any.
Q. So help me understand, Doctor, you've issued an opinion in this case that the Prolift device is

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safe and effective. How would I know when a device is not safe and effective?
MS. ROBINSON: Object to form.
Q. What objective standard are you using -- what objective standard would you use to determine that a device is not safe and effective?
A. I asked (sic) and answered that for you already.
MS. ROBINSON: Object to form.
Q. So what was your answer, because I missed it?
A. Okay. I'll say it nice and slow.
Q. Okay.
A. When you said that a device has a hundred percent erosion rate, what I said to you, is the first question would be to ascertain why that is. The characteristics of the device, the implantation system, the patient selection, comorbidities, other related factors to how that device is used. Okay? An understanding of that conceptually, it's not hard to do. It's actually straightforward.
Then to go to the literature, do other people see the same thing, published literature, textbooks, conferences, meetings; am I the only one seeing this or is this a national trend? From

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there, using all of the compendium of information ahead of me, then I can come to a logical conclusion.
Q. So if, after looking at all that data and determining that it wasn't anything to do with the way the device was being implanted or surgical technique or any outside factor, what rate of erosion would be unacceptable to you to where you would determine that that device is no longer safe and effective?
A. Again, it's not a number. This is not a number situation. You can't assign numbers to the situation. It's the gravity of what it is. Certainly if a device had a hundred percent erosion, there would be tremendous questions and it wouldn't be just from me. So that whole line doesn't make a whole lot of sense. Nobody would do it.
Q. What if the device had 50 percent erosion?
A. It's the same logic. Why? The most likely reason, okay, we'll continue down this pathway, is it probably is the end user is the one that has an issue with it. Probably the end user doesn't know how to use it. Doesn't know the indications. Doesn't know how to implant it.

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Q. Assuming that there's no issue with the end user, what's the rate at which you would determine that it's not safe and effective? There's no number; right?
A. There is no number. There is no number. At the end of the day, it usually is the end user; that's where the problems start and finish. Products, before they get approved, are trialed; okay? This is very obvious with the TVT, it's very obvious with Prolift. Complications, the problems were described for Prolift ten years before Prolift ever came on the market. Okay? Erosions, extrusions, infections, fistulas, hematomas, injury to bowel, injury to bladder, described, documented, 1996 to 1998. So we know already. We know all the things.
Q. So let me ask you, unfortunately, the same question with regard to efficacy rates. At what point would the failure rate be too high where you would say maybe this device is safe but it's not effective?
A. Again, you can't draw a number. But by the same token, you don't want to -- you don't want to offer repeated surgeries for patients. You don't

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want to create morbidity as a result of something that you've done. So you have to weigh the number with the effect of a number. Okay?
Certainly the higher the number -- it's intuitive. The higher the number the more likelihood there's some problem with it. But you have to interpret it based on the problem and what the problem is and why it's happening.
Q. Well, certainly the effectiveness rates of alternative surgeries or devices would be a factor that you would consider in whether or not a device like the Prolift is effective; correct?
A. Right. You could look at competitor products and efficacy.
Q. And so how different would the efficacy rate need to be between the Prolift and an alternative procedure before you would say that's not -- that's not -- that the Prolift isn't effective? It's the efficacy rates are too different. Is there a number or not?
A. No. There would be statistical significance. In other words, if you compared four products and one showed statistical significance, then that would suggest that one product might be better. Like

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augmented grafts in the anterior compartment, you can look and say, yeah, an augmented graft is better than no graft. So we know that a graft is better, more efficacy. The problem with your question on erosions is that we only have a numerator. We know how many erosions there are. We don't know the denominator in a lot of cases. And that number is extremely hard to know when it's significant or not. So numbers are very difficult to interpret and need to be in each respective context.

Q. Doctor, do you have -- strike that.

Doctor, do you know whether or not the amount of mesh placed in a woman's pelvis for the treatment of prolapse has an impact on the intensity and duration of the foreign body reaction and the inflammatory response? Do you have any opinion on that?

A. Does the amount of mesh -- certainly for any foreign body placed, there's going to be a foreign body reaction. That would be expected. Mesh is a foreign body, you do a sling, there will be a reaction. Certainly there can be more with more mesh placed. There's more foreign body. But mesh is a foreign body; it's synthetic.

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Q. So you would agree with me that as a general principle, the more mesh there is, the greater the foreign body reaction and inflammatory response?

A. Inflammation is a part of healing, which is a normal response to an implant being placed into the body, which will then be replaced with scar over time. It's not necessarily a bad thing.

Q. That's not my question, though. My question is: Would you agree, in general, that the greater amount of mesh material there is, the greater the intensity and duration of the foreign body reaction and inflammatory response?

A. No.

Q. No?

A. No.

Q. You don't think the amount of mesh material has any bearing on any of -- either of those things?

A. No, I think that all grafts will have a reaction. They will have a response with inflammation, with scarring, and foreign body reaction to it, be it autologous or cadaveric or mesh.

Q. So you don't think that the amount of inflammatory -- strike that.

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You don't think that the intensity and duration of the foreign body reaction and inflammatory response with, say, a total Prolift is greater than that of, say, a TVT that's implanted?

A. Well, there's more mesh placed in a TVT, yes. But that degree of reaction would only be determined if you biopsied and removed those meshes. Part of these reactions are normal responses to healing. Inflammation is a normal response to healing. You would expect that.

Q. Right. I'm not asking whether or not inflammation is a normal response or not. I'm just asking a very simple question of whether there would, in general, be a greater inflammatory response with a total Prolift as opposed to a much smaller mesh like TVT. Can you answer that question yes or no?

A. So you're saying a microscopic inflammatory response or inflammatory cells that are present?

Q. I'm talking about a general inflammatory response and foreign body reaction.

A. There will be a more localized inflammatory response, but that's part of the healing process and incorporation process for mesh because more mesh is

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used.

Q. Am I correct that you don't hold yourself out as an expert with regard to the design of medical device kits for the treatment of prolapse?

A. No, I'm not an expert.

Q. Am I correct in that I wouldn't expect you to offer any opinions with regard to the design of the Prolift?

A. No.

Q. I'm not correct or I am correct?

A. You are correct.

Q. Same question with regard to the Gynemesh PS.

A. Correct, I have no opinions on design.

Q. Do you know what a DFMEA is, a Design Failure Modes and Effects Analysis?

A. I've heard of it, but I don't know the specifics of what it means.

Q. Do you know if you reviewed one with regards to the -- strike that. I'm not going to ask if you know.

I'm going to ask, have you reviewed one with regard to the Prolift or the Gynemesh PS device?

A. No.

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Q. Am I correct that you don't hold yourself out to be an expert with regard to the type of mesh used in the Prolift?
A. Other than knowing its basic characteristics and the type one macropore monofilaments, no.
Q. Am I correct in that you don't hold yourself out to be an expert with regard to whether the mesh pore size in the Prolift -- strike that.
When you're forming your opinions with regard to pore size of the mesh, is your assumption that the only standard that matters is the Amid standard, which is 75 microns?
A. Yes, I use that.
Q. Is that the only standard that you use?
A. That's the only standard I use.
Q. Do you know when that standard was developed?
A. I don't recall off the top of my head. I would guess by saying mid-2000s, like 2005 to 2007 or so.
Q. Do you know whether or not the Amid standard was developed to be applicable to hernia meshes or pelvic floor meshes?
A. I thought it was to be applicable to all meshes. A lot of meshes from type one to type four

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and many of them were used for other reasons.
Q. Do you know if there are any more recently updated standards for pore size other than the Amid standard?
A. There certainly may be. I don't know them.
Q. Have you ever specifically studied the question of whether or not a one-millimeter pore size under strain is of any significance with regard to the Prolift or Gynemesh PS device?
A. I have not specifically answered that question.
Q. Do you know what Ethicon thought internally about the significance of having pores greater than one millimeter when in actual use?
A. No.
Q. Would you defer to the scientists that developed the Gynemesh PS and Prolift regarding that question?
A. I would defer to the literature, if there were papers that described that being of significance: Our core textbooks, Campbell's Urology, which I looked at and reviewed last night; and in the most recent edition there's no discussion of pertinent pore size other than the Amid

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classification.
Q. So the textbook that you're referring to -- would you say that again -- Campbell's Urology, was it?
A. Yes.
Q. What year was that published?
A. 2015.
MS. ROBINSON: The year you're referring to; right?
THE WITNESS: Yes.
Q. Do you know whether or not scientists internally at Ethicon believed that the Amid standard is actually outdated?
A. No, I don't.
Q. Would that have any significance to your opinions in this case at all?
A. No.
Q. So it wouldn't affect your opinions in any way whether or not the engineers who are actually responsible for designing and developing mesh at Ethicon actually thought that the Amid standard was outdated for pelvic mesh?
A. No, I think that the body of literature speaks for itself. The successes over time have

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been well described, its low erosion rates.
Q. Do you know what the weight is in grams per meter squared of the Prolift mesh?
A. I can certainly look that up.
(Witness reviews document.)
A. Yes.
Q. What is that?
A. Your question was?
Q. Do you know what the weight of the mesh is in the Prolift device in grams per meter squared?
A. It's 4.36 milligrams per cubic centimeter.
Q. You're reading from your report? What page?
A. 21. Under Gynemesh.
Q. Oh, okay. That's in milligrams per centimeter squared, not grams per meters squared, is what threw me off.
Do you know whether or not Ethicon has put any mesh on the market since the release of the Gynemesh PS mesh which is heavier in weight than the Gynemesh PS mesh?
A. No.
Q. Would you agree that the Prolift mesh, once placed, can become scar plated?
A. Can become what?

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Q. Scar plated?
A. All pelvic floor grafts can develop scar. That's part of how they heal.
Q. So is the answer to my question, yes, that once the Prolift mesh is placed, it can become scar plated?
A. No, the answer is all pelvic graft implant sites can develop scar.
Q. I'm not asking about all meshes. I'm asking specifically about the Prolift mesh.
A. Prolift can have -- can heal with scar formation.
Q. So it can become scar plated; is that accurate?
A. No. I said pelvic mesh can become scarred.
Q. Scarred but not scar plated?
A. Right.
Q. Would you agree that the scarring around the mesh can harden the mesh of the Prolift?
A. That's part of scarring.
Q. So is the answer to my question yes?
A. Repeat your question.
Q. Would you agree that the scar around the Prolift mesh can harden the mesh?

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A. It can harden the tissue by creating scarring, and the mesh is part of the tissue.
Q. And, in fact, sometimes that scar tissue can cause pain; correct?
A. There are a multitude of reasons for pelvic floor pain. Scarring is one of many. More people with pain actually have extrusions than they do the scarring.
Q. But there are instances where the -- where scar plating around the mesh can cause the patient pain or discomfort with sexual intercourse; correct?
A. Scarring, in general -- there's really -- scar in general can cause pain in patients and it's seen with all pelvic surgeries. But extrusions are much more commonly associated with pain.
Q. But you'd agree with me -- in fact, in -- there's been at least one of your -- one patient that's seen you that had scar plating surrounding the mesh where you recommended an excision of that mesh and concluded that it might give that patient some relief from her pain; correct?
A. I'd have to look at the specifics of what that case was, what were the specifics.
Q. So you don't remember any time during your

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career when a patient came to see you with a mesh with scar tissue around it, and you told that patient that removing that scar tissue may cause a relief of their pain symptoms?
A. You're talking about a lot of different things. And let me take a step back. You're talking about scar plating, okay, which is different than scarring. Scar plating can be an isolated issue. Scar formation as you're talking about in this particular patient may be an isolated spot where there was pain or erosion, extrusion, and certainly, in those patients with obvious point pain and/or an erosion, that that can be treated and it may need to be treated surgically.
Q. So it may -- it's possible that a patient may have scar tissue surrounding the mesh causing pain that may be treated successfully and resolve that pain?
A. They may have an isolated area as such that's associated with their pain. But as I said, usually this is in the setting of erosion and not in isolation. Usually it's in the setting of erosion. And the same that we've seen with our own meshes removed in patients with inflammatory reactions or

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lack thereof.
Q. But you would agree that scarring surrounding the mesh can occur even in the absence of erosion or exposure; correct?
A. You can have scarring in isolated areas of mesh. You can have scarring in isolated areas of biological grafts that cause pain.
Q. Do you know if the term "scar plating" had any significance to Ethicon internally among its doctors and scientists?
A. No.
Q. Would you agree that the Prolift mesh, through the process of creating scar tissue and fibrosis forming on the mesh, this process can also be accompanied by contraction of the mesh?
A. Contraction is described with Prolift. It can contract up to 20 percent, is expected with that. It's part of its healing process. That was well described by Ethicon in their physician education materials over the years, 2005, 2007, physician monograph, which leads to proper positioning of mesh so that we limit issues with pelvic pain, scarring, plating, things of that nature.

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Q. Are you familiar with opinion 513 of the joint opinion of ACOG and AUGS?
A. You'd have to show me where you're referring to.
Q. Well, I'll represent to you that a portion of the committee opinion says that the mesh kit should only be used in high-risk individuals for which no other options are available or appropriate. Do you agree with that opinion, or do you disagree with that opinion?
A. I'd like to see it with my own eyes and make comment. What were you referring to again?
Q. I'm referring to -- I don't think you need to look at the document, Doctor, you can answer as a hypothetical question.
Assuming that the opinion 513, the joint opinion of ACOG and AUGS states that the mesh kit should only be used in high-risk individuals for which no other options are available or appropriate; do you agree or disagree with that opinion?
A. I think that's very vague. You know, what's a high-risk individual?
Q. So am I correct that you can't answer yes or no whether you agree or disagree with that opinion?

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A. It's a very vague opinion, okay? It's very vague. What's a high-risk individual.
Q. So you would agree with me that you can't answer yes or no to that question because it's vague?
MS. ROBINSON: I think he would be more comfortable answering the question if he had the paper so he could see the context in which the opinion is rendered.
MR. FAES: I'm not interested in his comfort level.
MS. ROBINSON: No, I understand that. But I think it's only fair that you provide him the opportunity --
MR. FAES: No, I don't have to provide him. The question stands.
BY MR. FAES:
A. You can read me the question back.
Q. So my question is: Assuming that opinion 513, the joint opinion of ACOG and AUGS, states that the mesh kit should only be used in high-risk individuals for which no other options are available or appropriate; do you agree or disagree with that opinion, or can you not answer one way or the other?

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A. I disagree with that opinion because -- well, I'll leave it there.
Q. Why?
A. Because it's a very vague and open-ended, up-for-interpretation statement. Would you ever operate on a high-risk patient? Are they high risk because of their comorbidities -- coronary disease, diabetes, hypertension, obesity, parity, smoking, prior prolapse surgery? What makes them high risk? There's no definition of what's a high-risk patient. And if a high-risk patient is that kind of patient, then they shouldn't have any surgery. That statement is not enough to make a logical interpretation of what it means.
Q. Do you agree that the Prolift device should only be used in women for whom other approaches and other alternative approaches are not reasonable?
A. Each prolapse situation is unique. Each patient is unique. As I mentioned, their comorbidities, prior surgeries, the degree of prolapse, all these have to be considered before any such surgery is selected.
In general, Prolift will work better for patients with larger defects, particularly

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defects in the anterior compartment. It can also work for multicompartment, significant-size defects. And again, this is a decision made by the doctor and the patient in review of their complete medical records and exam.
Q. Just give me a second, Doctor. I'm looking for your IFU section.
Doctor, do you intend to offer an opinion in this case as to whether the warnings in the Prolift IFU were sufficient to apprise doctors of the risk of that product?
A. Yes.
Q. And what is that -- what is the opinion that you intend to offer?
A. The IFU -- initial IFU created in 2005 was sufficient to warn physicians of the necessary challenges with the product, as well as information that they already know from doing pelvic floor surgery.
Q. So it's going to be your opinion in this case that the Prolift IFU at all times was adequate to warn physicians regarding the risks of that product?
A. Yes.
Q. And, in fact, you actually specifically

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discuss your opinion on page -- starting on page 47 of your report, I think. Through 51.
(Witness reviews document.)
A. Yes.
Q. Do you know what standards Ethicon applied in terms of what warnings needed to be included in the IFU for the Prolift device?
A. I'm not a regulatory expert. I've never written an IFU. I've read a lot of them. But from my understanding, information in the IFU needs to be -- what information needs to be in the IFU is that that is unique to the product at hand.
Q. Do you -- in your practice, do you review each IFU that you use for a medical device prior to using it for the first time?
A. I may look at it, but I certainly don't rely on it. If I'm going to use a device, I should know what the IFU is before I even look at it. I should know what the device is. I should know how to use it or I shouldn't even think about using it.
Q. So is it your testimony that at times you don't review an IFU for a medical device prior to using it for the first time?
A. What I'm saying is if I don't know how to

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use -- how to intuitively use a device and have a good comprehensive understanding of the device, I probably shouldn't be using it.
Q. I understand that, but that's not my question. My question is, had there been times where you've used a medical device for the first time without having reviewed the IFU?
A. Yes.
Q. What medical devices have you used without reviewing the IFU?
A. Penile implants, new versions of penile managements that are based on the same versions that you know how to use and do. You know how to use that from your skills and training and education. You don't need an instruction guide to show you how to do that. You should know how to do that.
Q. Did you use the Prolift device for the first time without ever having reviewed the IFU?
A. I looked at it, but I certainly didn't rely on it or need it to use it.
Q. At your hospital in West Virginia University, does a physician need to be credentialed on a particular device before they're able to use it in the hospital?

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A. Depends what the device is. For the Da Vinci robotic surgery, yes. For other devices that are standard within someone's practice, probably not. For something that involves say a laser or a newer procedure with surgical equipment, maybe. It depends on what it is.
Q. Did -- at the time it was in use in your hospital, did a physician need to be credentialed on the Prolift prior to using it at West Virginia University Hospital?
A. No.
Q. So do you assume when you read an IFU that it's disclosing each of the risks and complications the company knew about with regard to the IFU? Specific to that device?
MS. ROBINSON: Object to form.
A. I expect it to include information that is unique to that device and its usage.
Q. Now, in your report, you note that the 2005 to 2009 Prolift IFUs do not specifically mention pain and dyspareunia, yet the IFU is still adequate. Is that accurate?
A. Yes.
Q. So you believe that putting the adverse event

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of pain in the IFU is not necessary?
A. Not at all, no.
Q. You believe that putting the adverse event of dyspareunia in the Prolift IFU is unnecessary?
A. Not necessary, no.
Q. But yet, Ethicon put those warnings in their IFU; correct?
A. They did over time, yes.
Q. So you believe that over time, Ethicon has put unnecessary warnings in their IFU?
A. No, I think they have put additional information in the IFUs; as you've seen through the years, they've become more comprehensive with more boldfaced terms, but each of those boldfaced terms were subjects that were well-known to physicians many years before Prolift ever came on market.
Q. But you just said a minute ago they were unnecessary. So which are they: Are they unnecessary or just additional?
A. They're just additional. But they're not necessary. And any user who knows how to do pelvic floor surgery knew those things.
Q. So they're additional unnecessary risks that are included in the IFU?

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A. No, they're -- it's additional unnecessary information of risks that are well-known to physicians.
Q. Why do you think Ethicon would choose to put unnecessary additional risks in their IFU?
MS. ROBINSON: Object to form.
A. I think they're putting additional information into their materials to be more complete, but that doesn't mean being complete is necessary.
Q. So you'd agree that the later version of Prolift IFU that includes pain and dyspareunia is more complete than the prior versions that didn't include those terms?
A. It makes the IFU now look like a textbook chapter of information that was already known to physicians who practice that. Again, not necessary, known, well understood, well described, but now it makes that with more complete information.
Q. Well, you'd agree that including too many things can actually be more dangerous to a product; correct?
MS. ROBINSON: Object to form.
A. I don't know if it's more dangerous. I think

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it -- it gives people more things to read.
Q. You don't think that providing unnecessary warnings that people already know about distracts people from the risks that they need to know about that they don't already know about?
MS. ROBINSON: Object to form.
A. Does it distract them from the risks?
Q. Yes.
A. I don't think anyone is going to read them who already knows that. They will look at that and say, well, we knew this already. I don't need to see this again, I know this. It's well described in my textbooks. I know it causes pain. I know it causes dyspareunia. I know that.
Q. But you would agree that there are different types of pain, that not all pain is the same; correct?
A. There are different types of pain, yes.
Q. Which do you think is the more appropriate Prolift IFU, the one that includes dyspareunia and pain as a potential adverse event or the one that doesn't?
MS. ROBINSON: Object to form.
A. Which is more --

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Q. Which is more appropriate?
A. Which is more appropriate? I don't have an opinion as to either of them. I think the one that has it is more complete, but the initial one was certainly appropriate because any pelvic surgeon knows that. These are risks of pelvic floor surgery. That's well-known and well described.
Q. You keep saying that it's well-known and well described and physicians know that, and you've said that many times in your report; correct?
A. I have, yes.
Q. Have you ever studied the question of what risks and complications were known to doctors across the country with various background, levels and experience with regard to the use of the Prolift?
MS. ROBINSON: Object to form.
A. I'm not sure what you're referring to by survey or what. What are you referring to?
Q. Have you ever done any kind of survey or used any kind of formal methodology to determine what physicians did or did not know with regard to the risks of the Prolift?
A. You know, physicians have done a variety of different things to learn about procedures from --

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MS. ROBINSON: First you can answer his question on whether you have done any survey yourself.
A. No, I have not done any survey myself.
MS. ROBINSON: Then you can explain.
A. Physicians have used a wide variety of ways to learn about procedures, from attending meetings, symposia, reading review articles and textbooks and such. They have a multitude of sources in front of them to know risks and things that are pertinent to them.
Q. So have you done any kind of formal analysis to determine, for example, what percentage of Prolift users knew or didn't know that pain was a potential risk from the Prolift IFU -- or chronic pain?
A. No, I have not surveyed anyone or any -- any group as to what their knowledge of the present Prolift IFU was. But I know that anyone who reads a core textbook in urology or gynecology, even written as back as 1998, knows that pelvic mesh can be associated with all of the complications that you've mentioned, including pain.
Q. Have you done any type of formal analysis to

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determine what percentage of pelvic floor surgeons using the Prolift knew or didn't know about the risk of chronic dyspareunia with the Prolift?
A. All I know is what -- the information provided in their textbooks, which was provided well in advance of them seeing a Prolift IFU. I know that in 1998 in Campbell's Urology, there's a complete discussion of the risks of pelvic floor surgery. I know in 1997, in Danforth's Obstetrics and Gynecology book for the gynecology colleagues that there's extensive discussion for the risks of pelvic floor surgery, including mesh-based surgery. I know that in Mickey Karram's 1999 book of urogynecology that there was access to that.
So what I'm saying is that for the eight to ten years prior to Prolift IFU, that all physicians, if they've opened a textbook, had access to this information.
Q. But my question is specifically, you haven't done any kind of formal analysis as to what percentage of physicians who are using the Prolift at any time knew or didn't know about the risk of chronic dyspareunia with the Prolift device?
MS. ROBINSON: Object to form. Asked

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and answered.
A. I had answered that for you completely.
Q. I don't think you have, Doctor. Is the answer, no, you haven't done any kind of formal analysis --
A. I have not --
MS. ROBINSON: Same objection. And --
Q. -- and you don't know the percentage?
A. I have not done --
MS. ROBINSON: -- argumentive.
A. -- any formal analysis.
MR. FAES: He answered it with regard to the pain but not dyspareunia. Now he's answered it with regard to dyspareunia.
Q. So my next question is, Doctor, do you believe, in 2009, if a doctor implanting the Prolift device stated that he didn't know about the risks of a chronic pain or chronic dyspareunia with the Prolift, do you believe that that doctor has fallen below the standard of care?
A. You know, I can't discuss what the standard of care is, because the standard of care relates more to malpractice than anything else. It would be prudent for any physician to understand pelvic floor

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anatomy, pelvic surgeries before he or she ever undertakes a prolapse surgery. It says that in the IFU early on, that users should be familiar with the risks and benefits of pelvic floor surgery of which pain is one of them. So it's pretty up front and out there for them. They should know that.
Q. As you sit here today, do you have any understanding of any standard whatsoever as to what risks and complications are supposed to be disclosed in an IFU?
A. Again, I'm not a regulatory expert, but what I do know and what I believe is that risks that are unique to a specific product at hand, different than any other product, should be disclosed in an IFU.
Q. So am I correct that you aren't aware of what the legal standard is for what a company needs to include in an IFU with regard to risks and complications?
A. Again, I'm not a regulatory expert, so I don't know the specifics of what they have to, but the general knowledge that I know is that it has to be specifically unique to the product at hand.
Q. Have you ever engaged in the study of what -- strike that.

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Let me ask it a different way. Have you ever studied the question of what needs to be included in an IFU for a medical device? Have you engaged in the study of that question?
A. No.
Q. Would you agree that excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening is a potential adverse reaction of the Prolift mesh?
A. It's a potential adverse reaction of any pelvic floor graft.
Q. Okay. Again, I'm not asking about any pelvic floor graft. I'm specifically asking about the Prolift. Is that a potential adverse reaction of the Prolift mesh?
A. It is a potential adverse reaction of any pelvic floor procedure involving a graft.
Q. Again, I'm not asking about any pelvic graft. I'm specifically asking about the Prolift mesh. Is that a potential adverse reaction of the Prolift mesh?
A. Yes.
Q. Do you believe that that would be a reasonable warning to include in the Prolift IFU?

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A. No.
Q. So if Ethicon were to put that in their Prolift IFU, you believe that that would be unnecessary?
A. Right, because it was known ten years earlier.
Q. If Ethicon put that adverse reaction in their Gynemesh PS IFU, do you believe that would be unnecessary?
A. Unnecessary, known prior.
Q. So if Ethicon did put that risk in their Gynemesh PS IFU, you believe that they have placed unnecessary additional information in their IFU?
A. No. I believe that this is additional information that was known to physicians already. They knew that already, so it was not necessary.
Q. What are you -- what are you basing your opinion on that physicians already knew about that; about the risk of excessive contraction or shrinkage of tissue surrounding mesh, vaginal scarring, tightening and shortening?
A. Well, when Ulmsten did his original papers in 1994 and 1996 describing -- actually '95, the intravaginal slingplasty, and he talked in that

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paper about defective healing, he talked about the importance of what happens when you have defective healing; you have pain, you have sinus tract formation and scarring. He talked about the forces that the sling must be placed under to create appropriate tension. And he says that the sling, which certainly can be applied to Prolift, should not elevate the urethra but should be tilted under the organ, otherwise there is passive kinking and postoperative voiding dysfunction. And these adhesion forces act immediately so the correct position is important. And this was ten years prior. This is 1995.
Q. And do you have any kind of opinion as to what percentage of physicians who use the Gynemesh PS or the Prolift device has actually reviewed that Ulmsten 1995 study?
A. Again, these were the first studies that have come out. Over the three years, from 1995 to 1998, the concept of erosion, extrusion, obstruction, hematoma, pain, scarring, has been described in multiple publications. And then, of course, there are others from 2000 -- from 1998 to 2000.
So now you have a five-year period for

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physicians to certainly be aware of this, at their meetings, through case reports, you know. And these are significant studies. The number of patients in this study -- this is not a case report. This is 50 patients studied here. Then Ulmsten again, two years later, 63 patients. Here's Falconer, 1996, 75 patients, failures, rejection. Here's -- here's 1998, Ulmsten again, 131 patients. So here's -- Nilsson, 2001 -- scratch the discussion of Nilsson.
So you have the body of papers over a three-year period already telling physicians these are problems that can occur with mesh surgery. You need to know about this. And certainly these are in the textbooks as well.
Q. Am I correct that you cannot state to a reasonable degree of certainty the percentage of Prolift and Gynemesh PS users who knew or did not know about the risk of excessive contraction or shrinkage of the tissue surrounding the mesh?
A. I have no idea what each user of Gynemesh knows. I can't be in their heads to know what they know and what decisions they make in advising their patients.
Q. So same question, am I correct that you can't

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state to a reasonable degree of medical certainty what percentage of physicians who use the Gynemesh PS and Prolift know about the risk of vaginal scarring, tightening or vaginal shortening with the mesh?
A. No, I can't state how many. But certainly these are issues that are relevant to their board certifications and such; and to go on further, sure, female pelvic medicine and reconstructive surgery now has part of their curriculum questions and such on this, certainly that can be assessed. You would have to go to that body of information.
MR. FAES: I'll object and move to strike after the answer I don't know how many.
Can we go off the record for a second.
(Discussion held off the record.)
(A brief recess was taken from 5:45 p.m. to 5:48 p.m.)
BY MR. FAES:
Q. We're back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. Is it possible that you might know about a complication with the Prolift device that another

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doctor might not know about?
A. I shouldn't.
MS. ROBINSON: Object to form.
A. I shouldn't. We all should know the same thing.
Q. But it's possible that you may; correct?
A. Well, we all have the same knowledge to learn from, our textbooks, our materials, pelvic floor surgery, chapters in our core books. We all should know the same things.
Q. You would agree that one way to ensure that all doctors know the same things about the risks of the Prolift device is to include all the risks that the company knows about in the IFU or instructions for use?
MS. ROBINSON: Object to form.
A. No, that should be in their textbooks. It should be -- things that are unique to the product should be in the IFU. Anything else is just additional known information.
Q. So you don't agree that that's one of the ways that the company could ensure that everybody knows about the risks?
A. They could ensure that, but the physician

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should know that already. They should know that from their body of knowledge.
MR. FAES: I'll object to -- object and move to strike the portion of the nonresponsive answer.
Q. Now, Doctor, you've performed approximately a hundred Prolift procedures; right?
A. Yes.
Q. And you removed pelvic organ prolapse meshes in approximately 10 to 20 cases; right?
A. In -- much more than that. If we're talking about TVT and TVT-O and other patients referred to me for mesh removals.
Q. Let's back up a minute. My understanding was that with regard to pelvic organ prolapse meshes from your prior testimony, you had removed approximately 10 to 20. I'm just talking about pelvic organ prolapse meshes. Is that accurate or not accurate?
MS. ROBINSON: That misstates his testimony.
BY MR. FAES:
Q. I don't know if it does. Let me withdraw that and I'll reask the question.

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My question Doctor is, approximately how many pelvic organ prolapse meshes have you removed in the course of your career?
A. I'd say 10 to 20.
Q. So you put in about a hundred and you removed about 10 to 20?
MS. ROBINSON: Object to form.
A. I put in a hundred of my own. I've had three patients with extrusions, two were trimmed in the office. One was trimmed in the OR, because she had a bladder tumor so we did that under anesthesia to deal with her bladder tumor. And I don't count those in the 10 to 20 removed because those were done in the office. The ones I had done, the 10 to 20, are patients who were referred with a variety of different complaints or problems from other practices.
Q. Right. But in terms of your surgeries for pelvic organ prolapse products -- strike that.
In terms of your surgeries for pelvic organ prolapse meshes, about 10 to 15 percent is taking them out and about 90 to 85 percent is putting them in; is that fairly accurate?
A. No. Of my own meshes of my own patients, as

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I said, I've only had three that I have had issues with.
Q. I'm not talking about just your patients. I'm talking about your surgeries for pelvic organ prolapse meshes in general. Is it correct that for all of your pelvic organ prolapse mesh surgeries, in general, approximately 10 to 15 percent is taking them out and approximately 85 to 95 is putting them in?
A. In most cases I'm putting them in, yes, and the ones I'm taking out, I'm taking out for patients referred to me for a variety of reasons. They're not my own cases I'm removing mesh from.
Q. I understand that, Doctor.
A. Yes.
Q. But with that caveat in mind, is that correct?
A. Yes. I need to take a break. I'm on vibrate so I have a page.
MR. FAES: Off the record.
(A brief recess was taken from 5:54 p.m. to 5:55 p.m.)
BY MR. FAES:
Q. Back on the record after a short break. Are

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you ready to proceed?
A. Yes.
Q. Have you ever made any effort to confirm that your understanding of what needs to be in the Prolift and Gynemesh PS IFU is consistent with what other doctors believe should be in the IFU?
A. No, I have not done any independent looking.
Q. In doing your work in this case, were you ever curious as to what the regulatory affairs professionals department in Ethicon, who are the professionals that are required to make sure the IFU complies with FDA regulations, were you ever curious as to what they believe should be in the IFU?
A. No, I'm not a regulatory expert. But no, I -- it never crossed my mind to question them.
Q. What about with regard to what the medical directors at Ethicon or medical doctors thought should be in the IFU?
A. No.
Q. Would you agree with me that if Ethicon medical affairs knew that there was a potential risk or complication attributable to the Prolift mesh or the Gynemesh PS mesh itself, which, if it occurred, could cause severe permanent injury to a woman, that

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those risks should be disclosed in the IFU?
A. If there were. If they were not known, and certainly if they were not reported in any medical literature, then, yes, that would be information needed to be known. Being that these complications and these issues come from literature that we have, then we should already know that.
Ethicon should never know something that we didn't know first from the field and from trying. Again, from these articles ten years before Prolift was ever released. We knew and we saw the problems and the challenges ten years before they happened and became mainstream.
Q. Would you agree that one of the risks of Prolift and Gynemesh PS device is that the Prolift and Gynemesh PS can lead to complex mesh erosions?
A. Any mesh that's used can have mesh erosions and the complexity is going to depend upon patients healing, comorbidities, other issues; that's certainly obvious to all physicians.
Q. So you would agree that's one of the risks?
A. That's one of the risks, but it's well-known.
Q. Would you agree that one of the risks of the Prolift device is neuromuscular problems including

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acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area?
A. They're extremely --
MS. ROBINSON: Object to form.
A. They're extremely rare complications. I was fully looking at this in Campbell's last night, and there were two citations, one by Stanford and the other one I'm losing, where they talk about single numbers of patients that had chronic groin or thigh or leg pain. Single numbers of patients, so extremely rare.
Q. But the answer to my question is yes, that's a potential adverse reaction from the Prolift mesh?
A. Extremely rare, but yes.
Q. Would you agree that the approach for -- strike that.
The approach for the Prolift posterior mesh requires passage of the mesh through the obturator foramen; correct?
A. Actually, it goes -- are you talking about the anterior pass or the -- state your question again.
Q. Would you agree with me that the placement of the Prolift posterior mesh requires passage of the

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mesh through the obturator foramen?
A. I don't understand your question, and I'll tell you why. In the anterior Prolift, there are two passes, an anterior pass and a posterior pass, of the anterior mesh. That goes through the obturator foramen for an anterior kit. For posterior kits, it goes directly through the ischia rectal fossa through the sacrospinous ligament. So that does not. If your question was in a posterior kit, the answer is no, it does not go through the obturator foramen.
Q. So in an anterior kit, it passes through the obturator foramen; right?
A. That's correct.
Q. And it essentially follows the same path, anatomical path that a physician would follow if they were implanting a TVT-O device; correct?
A. The anterior much more than the posterior. The posterior pass of the anterior mesh goes through the sacrospinous ligament. It goes near it. And that's a bit lower than they would be placing the TVT or TVT-O. The anterior is much more likely. It's higher up.
Q. Would you agree that in 2004, when the

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Prolift device was first introduced, that passage of the mesh through that obturator foramen was a relatively new surgical approach?

A. It's a variation on things we've been using in the past. It's variations on the staining needles, it's variations on passing the needles under vision or with tactile sensation. Variations of things we have already known what to do.

That posterior pass is an easy pass, and it can certainly be visualized as that is passed if you set the retractors up correctly.

Q. You mentioned some staining needles and some other things, but with regard to the passage of mesh through that anatomical space, that was a relatively new concept at the time the Prolift was introduced in 2004; right?

A. Yes.

Q. It had only been around since approximately with 2001; right?

A. Or so, yes.

Q. Would you agree that since the passage of mesh through the obturator foramen space had only been around for about three years at the time the Prolift device was introduced, that the long-term

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effects of placing mesh in that area were not well understood?

A. There's really not a lot of structures in that area that have a need for additional understanding. That posterior pass is just to allow the mesh to sit posteriorly. It's nothing -- there's nothing additional and new that wasn't already known. The risks of injury to bowel, bladder, nerves, blood vessels, still known to all physicians who know the anatomy.

Q. So you don't believe that the fact that a permanent mesh placed in that area could introduce new and different risks, long-term risks that the medical community didn't know about?

A. No. No. Pain, infection, erosion, fistula, all well described beforehand. Nerve injury, nerve entrapment described in 1998 in Campbell's for variations of other types of suspensions that were performed.

Q. What other types of suspensions?

A. Gittes, Raz, Pereyra. These were all needle suspensions that were used at the time. Then there were bone anchor procedures to the pelvic side wall which fell out of favor because of osteitis and bone

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infection. The thought was, let's not do that, let's just use the obturator foramen since there is nothing anteriorly or medially, all the blood vessels in there are lateral, so that would be a good area to pass through. It was very intuitive based on what we already knew.

Q. Would you agree that levator spasms are a potential adverse reaction of placing a foreign material like Prolift mesh in that area?

A. No. Levator spasms are actually more common after the posterior pelvic floor surgery, rectocele repair, levatorplasty, perineal body resections.

And that's actually been well studied, that complications of pelvic pain and dyspareunia when patients -- when those procedures are not performed, meaning perineal body resection and levatorplasty, that the risk of dyspareunia is significantly lower.

Q. So you don't believe that levator spasms from a mesh being placed in the obturator foramen is a potential risk of Prolift mesh?

A. It's a risk of any posterior pelvic floor surgery, especially those that are involving those additional procedures I mentioned. Okay?

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Q. So you're --

A. If you put a mesh in in addition to doing those things, you significantly heighten these risks. A lot of the patients who had a posterior Prolift often had these other procedures as well. When those were omitted, these patients did quite a bit -- did quite a bit better.

Q. Would you agree with me that considering that native tissue repair for the repair of pelvic organ prolapse is an option for many women, that makes sense to use vaginal mesh judiciously for vaginal mesh repairs of pelvic organ prolapse?

A. Certainly native tissue repairs are a choice, but when compared to polypropylene mesh, polypropylene mesh may afford patients a better anatomical and a better subjective sense of bulge reduction.

Q. But my question is, given that those options are available, does it make sense to use vaginal mesh judiciously for vaginal repairs of pelvic organ prolapse?

A. As I said earlier, many times, each patient is a unique patient. You have to consider the degree of deficit, their prior surgeries. Their

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past medical history, physical exam findings, their desires, age, expectations. It's an individual decision.
Q. So in women with recurrent prolapse, particularly in the anterior compartment and those with medical comorbidities that may preclude more invasive and open laparoscopic procedures, they may be good candidates for vaginal mesh; is that what you're saying?
A. No. First of all, I wouldn't repair prolapse laparoscopically, I might do an abdominal sacrocolpopexy. It's going to depend on, again, the overall health of the patient. Again, you have an 80-year-old woman with multicompartment prolapse who failed a repair, we'll close her vaginal wall. We'll do a colpocleisis, that's the best procedure for her. That's not a patient who should have mesh, but you only know that by treating each patient as an individual entity.
Q. You know how the Prolift device is cut by Ethicon and Johnson & Johnson?
A. No.
Q. So since you don't know how it's cut, I wouldn't expect you to offer any opinions in this

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case regarding how the cutting method affects the physical properties of the mesh?
A. No.
Q. Same question for the Gynemesh PS; do you know how the Gynemesh PS flat sheets are cut?
A. No.
Q. I wouldn't expect you to offer any opinions in this case regarding how the cutting method for the Gynemesh PS affects the physical properties for the mesh.
A. No.
Q. Let me ask you something specific about the Prolift IFU. What specific information do you believe that the Prolift IFU actually needs to say in the adverse reactions section in order to warn doctors about the complications?
MS. ROBINSON: I'm going to object to form. You have a specific IFU you want him to refer to?
MR. FAES: No, I'm asking what he believes needs to be in the Prolift IFU adverse reaction section.
MS. ROBINSON: Not as to a specific Prolift --

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MR. FAES: What?
MS. ROBINSON: Not to as to a specific IFU.
MR. FAES: No, I'm basically asking what he -- if he was writing the IFU, what adverse reactions does he think need to be in there.
A. Well, I don't write IFUs, and I'm not a regulatory expert of what needs to -- the wording of such needs to be in the IFU, but I believe that what's here in the 2005 IFU is reasonable and materials that should be known by all physicians who would perform this procedure.
Q. So is it your opinion that everything that's included in the adverse reaction section of the 2005 IFU needs to be in there?
A. Well, there's words here that are written here and there's information that's implied from this material. So you have to read the words and understand what they mean. So pain is not mentioned here. Nor is dyspareunia mentioned here. Nor is vaginal shortening or contraction, but these are -- I'm sorry, the contraction is mentioned there.
But for any patient to have these particular symptoms, we will see erosion, extrusion,

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scarring, these are -- these are the ways they will present, and we knew that in 1996 with Ulmsten's original paper that his patients with erosions and extrusions had pain. That's how they came in. So pain is how these will manifest and it's known that they can be painful. And that's understood.
Q. My question is a little different. My question is specifically, do you believe that everything that's included in the 2005 Prolift IFU adverse events section needs to be in there? Or is there any, as we've talked about earlier, is there any unnecessary or additional information that doesn't need to be in there?
A. This is the information that must be in here. These type of adverse events, these are things that must be in here. Punctures, lacerations of solid organs, blood vessels, nerves, absolutely has to be in there, although they are known to all physicians who do this kind of surgery. The others above are certainly things that you would expect as a result of using a mesh-based product. And the fact that pain is not mentioned and such, this is how these patients are going to present. They're going to present with pain and that's known, known to all

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physicians.
Q. So inflammation is a risk of the Prolift that's known to all physicians?
A. Inflammation is the risk of any pelvic floor graft procedure that's performed.
Q. But it's known to all physicians?
A. It's known to all physicians, yes.
Q. Then why does that need to be included in the IFU but things like pain and dyspareunia don't need to be included in the IFU? Why is that not extra information?
A. Because if a patient had significant inflammation, they would have pain. They would have dyspareunia from the meshes in the vagina. Inflammation will present with pain; adhesions will, fistulas will, erosions will, extrusion will. It's all presented with pain.
Q. Do all physicians know that adhesion formation is a potential risk of Prolift IFU?
A. Of any pelvic floor surgery.
Q. Then why does that need to be in the Prolift IFU but a risk such as vaginal scarring or shortening doesn't need to be?
A. Well, again --

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Q. Well, actually scarring is in there, so let me rephrase that.
A. Sure.
Q. So why does adhesion formation need to be in the IFU if all physicians know of that risk but a risk like vaginal shortening doesn't need to be in the IFU?
A. Well, adhesions can be the patient with multicompartment prolapse that you didn't know until you got inside. Maybe they had a cystocele and a large enterocele, and the enterocele had herniation, and the sac was opened and there's adhesions from a prior surgery that she had. That would certainly be important to know, that, hey, that may make this worse.
Q. Fistula formation, erosion, extrusion and scarring that implants -- strike that.
Fistula formation, erosion, extrusion, and scarring that results in implant contraction are all risks that physicians who implant the Prolift already know about; right?
A. Yes.
Q. But you believe that even though they know about those risks, they still need to be included in

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the IFU?
A. Yeah, I think it's reasonable that they be here.
Q. Doctor, I want to ask you specifically about page 20 of your report where you state Gynemesh PS mesh used in Prolift is an excellent synthetic mesh to be used in pelvic floor surgery. First, it is dynamic and has just the right amount of rigidity and flexibility. This allows it to mold well into the vaginal wall. Is that an opinion that you intend to offer in this case?
A. Yes.
Q. How did you determine what -- just the amount of rigidity and flexibility that a mesh needs for repair of pelvic organ prolapse in order for it to mold well into the vaginal wall?
A. Well, you have to try them. You have to try one. You have to do it. You have to see, once the trocars are placed, how does the mesh lay in the tissue that you propose it to. Does it lay comfortably? Is it -- is it bunched upon itself? Is it the appropriate size?
This is a very -- this is a very soft mesh. And something that certainly would fit very

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nicely into a space in the anterior posterior compartment.
Q. What objective standard are you using for your conclusion that the Gynemesh PS mesh has just the right amount of rigidity and flexibility?
A. Well, if you compare it to something like the original TVT prolene mesh, it doesn't weigh as much, the pores are larger, it's more flexible, you know. If you've used TVT -- original TVT mesh for a large prolapse case, it probably wouldn't fit as well. It probably wouldn't heal as well for patients.
This is something that really is incorporated well into tissues. It's soft, it's easy to mold. The extrusions that I've had are really very small and easily able to be trimmed. So it was the right -- the right product for the right situation.
Q. So you would agree that the TVT mesh doesn't have the same amount of rigidity and flexibility as the Gynemesh PS mesh; correct?
MS. ROBINSON: Object to form.
A. I think the Gynemesh PS is more flexible. I think it's better suited for prolapse repair.
Q. So if the Gynemesh PS has just the right

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amount of rigidity and flexibility, which allows it to mold well into the vaginal wall, does that mean that the TVT mesh does not have the right amount of flexibility and rigidity to mold into the vaginal wall?
A. No, they're done for different reasons. TVT is a urethral sling. It's meant for urethral mobility. Prolapse mesh is meant for a larger surface area and to do something different to reapproximate different structures that are lost in patients, meaning their fascial support, their pelvic floor fascial support. So you want something that's -- would be better incorporated and better tolerated.
Q. Well, you know that the Prolift+M device actually uses a different mesh that has a different amount of rigidity and flexibility; right?
A. Yes.
Q. Is it your opinion that that mesh doesn't have the right amount of rigidity and flexibility that allows it to mold well into the vaginal wall?
A. I've never used Prolift+M, so I'm not going to offer an opinion on that.
Q. You also state that the mesh is lightweight

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and allows for good structural integrity to support the native tissue. What objective standard are you relying on for your opinion that Gynemesh PS is lightweight?
A. Just based on its -- on its comparison to prolene mesh. And the predecessors before it that didn't do well, like Dacron and GORE-TEX and other things like that that never made it as graft material in the anterior compartment.
Q. So is it more accurate to say that the Gynemesh PS is lighter weight than the TVT mesh, or is it your opinion that it's lightweight?
A. I think they're both lightweight. I think the Gynemesh is a bit lighter weight than the TVT mesh.
Q. So what does -- what standard are you applying for when a mesh is lightweight versus not lightweight?
A. Just the Amid classification. Lightweight macropore monofilament is all potential mesh to be used in the pelvic floor. Some may be better than others. Some mold better.
Q. Well, the Amid requirement doesn't have a weight requirement in terms of grams per meter

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squared; right?
A. Yeah; but pore size and filament does, yes.
Q. So it's your opinion that any amount of filament mesh with a pore size greater than 75 microns is considered a lightweight mesh?
A. Yes.
Q. Doctor, earlier we were talking about pages 47 through 51 of your report which discusses the IFU, the Prolift IFU?
A. Yeah.
Q. Did you write a similar section with regard to the Gynemesh PS IFU?
A. No.
Q. Do you intend to offer an opinion in this case that the warnings in the Gynemesh PS IFU are adequate?
A. No.
MR. FAES: I guess I'll pass and reserve my limited time. Thank you, Doctor. I don't have any further questions at this time subject to follow-up.
(A brief recess was taken from 6:22 p.m. to 6:37 p.m.)

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EXAMINATION
BY MS. ROBINSON:
Q. Doctor, if you'll turn to page 2 of your report, I think it makes sense to start with some of the last questions that you were asked by Mr. Faes.
A. Yes.
Q. You've offered the opinion that Gynemesh PS, which is the mesh used in the Gynemesh PS as well as the Prolift device; correct?
A. Yes.
Q. That that mesh, you believe, has the right amount of rigidity and flexibility to be used in the female pelvic floor; correct?
A. Yes.
Q. And for female pelvic organ prolapse repair?
A. Yes.
MR. FAES: Object to the form.
A. Yes.
Q. Doctor, in rendering that opinion, were you considering your experience with other graft material that you had previously used in surgeries for pelvic organ prolapse?
MR. FAES: Object to form.
A. Yes.

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Q. And what surgeries had you previously used with graft material in pelvic organ prolapse that you would use to compare the type of rigidity and flexibility required for a repair?
A. Tutoplast pericardium, Pelvicol, cadaveric dermis, fascia lata.
Q. And based on your experience with those types of grafts, your -- you were able to render, in part, your opinions about the rigidity and flexibility of the Prolift and Gynemesh PS mesh?
MR. FAES: Object to form.
A. Yes.
Q. Did you also, in coming to the opinion that it had the right amount of rigidity for use in pelvic organ prolapse repair, rely upon scientific data and literature?
MR. FAES: Object to form.
A. Yes.
Q. And what is it about the scientific data and literature that you relied upon to help you come to the decision that Gynemesh PS mesh and Prolift mesh have the right amount of rigidity and flexibility for use in pelvic organ prolapse?
MR. FAES: Object to form.

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A. It's monofilament in nature. Its large pores. Its ability to be placed in the area in question and lie flat without any forces upon it.
Also, I also relied on information from colleagues, from textbooks, from meetings, opinion -- the key opinion leaders.
Q. And specifically, with regard to the body of scientific literature and the opinions of your colleagues and so forth, were you referring to the type of complication rates that are associated with the use of Gynemesh PS and Prolift?
MR. FAES: Object to form.
A. Yes.
Q. And do you find that the complication rates are all they -- strike that.
Have you found that the complication rates that have been reported in the scientific literature to support your opinions that the mesh itself has the right amount of rigidity and flexibility?
MR. FAES: Object to form.
A. Yes, I thought so.
Q. Similar questions with regard to your opinion that the mesh is lightweight and allows for good

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structural integrity necessary to support the native -- native tissue of a woman: What information did you rely upon in rendering your opinions about that?
A. Again, from personal experience with grafts, cadaveric, the different types I've mentioned before, personal experience, clinical experience, literature, colleagues.
Q. And their personal experience with regard to use specifically of the Gynemesh PS and the Prolift?
A. Yes.
Q. And the literature that you reviewed, specifically with Gynemesh PS and Prolift?
A. Yes.
Q. For example, have you found in your own clinical experience that the Gynemesh PS and the Prolift provides better structural integrity than cadaveric grafts, for example?
MR. FAES: Object to form.
A. Yes.
Q. Have you reviewed literature that supports your opinions on that?
A. Yes.
Q. And is that literature cited in the body of

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your report?
MR. FAES: Object to form.
A. Yes, it is.
Q. Similar, is -- does the literature that you have read, also support the fact that Gynemesh PS and the mesh which is the mesh used in Prolift, is a lightweight macroporous monofilament mesh?
MR. FAES: Object to form.
A. Yes.
Q. And that has been determined in the scientific literature; correct?
MR. FAES: Object to form.
A. Yes.
Q. It's been recognized even beyond the Amid-type papers; correct?
MR. FAES: Object to form.
A. Yes.
Q. And that's information that you're also relying upon for your opinions; correct?
A. Yes.
Q. You recall a line of questions that counsel asked you regarding your opinions with the use of the IFU; is that correct?
A. Yes.

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Q. Doctor, during the course of your day-to-day job, do you use IFUs for products in training your resident physicians?
A. I review the IFU with the resident to make sure they at least know what it is. At least once, so they know what it is.
Q. Okay.
A. But really it's their education and training, core textbooks that give them the information they need to know.
Q. But it's something that you're familiar with and you know that IFUs come with products; correct?
A. Yes.
Q. And doctors know that IFUs come with products?
A. Yes.
Q. And you make sure that your residents are aware of that; correct?
A. Yes.
Q. And you make sure they review the technique and description of how a product is used in the IFU; correct?
A. Yes.
Q. And is that something you go over with

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them -- and please, just remind me, do you actually have a -- a lecture sort of training sessions for your residents?
A. Yes. There are core lectures in urogynecology for the gynecology residents.
Q. And do you teach them?
A. I do. And also there are core lectures for our own urology residents, my residents, on this. So we cover the core aspects of these procedures, indications, contraindications, review of the IFUs, so at least they know what it is. When they see it in practice, they will know what it is or if some new product comes out, they will know what an IFU is.
Q. Is an IFU something that you've been familiar with throughout your entire career, essentially, as a physician?
A. Yes.
Q. You have attended -- well, do you attend meetings of other urologists?
A. Yes.
Q. Do you attend meetings of other urogynecologists?
A. Yes.

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Q. And are devices such as the Prolift device and the Gynemesh devices that are discussed at these meetings?
A. Yes, they are.
Q. And during any of these meetings, have you ever heard any of your colleagues express that the Prolift IFU was not sufficient to warn them of the particular adverse complications that could be associated with that product?
MR. FAES: Object to form.
A. No physician ever mentioned to me any issues, nor have I heard discussions in that area.
Q. If you look to page 50 in your expert report -- page 50 of the expert report, it does refer to regulatory -- a regulatory reference for IFUs; is that correct?
A. Yes.
Q. And have you reviewed that regulatory reference?
A. I have. I'm not a regulatory expert to know all the details of it, but from a general sense, I have. I have some understanding.
Q. And do you stand by the opinion that is in your report with regard to that regulatory

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requirement and guidance concerning the IFU?
A. Yes.
MR. FAES: Object to form.
Q. And is that, in part, what you relied upon in formulating your opinions about the adequacy of the Prolift IFU?
A. Yes.
Q. Now, have you ever seen an IFU for an anterior colporrhaphy?
A. It would have to be for a device.
Q. Okay. So there is none. For performing an anterior colporrhaphy, there is nobody that writes down for you from a device company about the potential risks and warnings of performing an anterior colporrhaphy; correct?
A. No.
Q. And is that the same with sacrospinous ligament fixation procedure?
A. Yes.
Q. Same with the hysterectomy; right, there's no IFU for that?
A. No, there is no IFU.
Q. You indicated, I believe, in your testimony that, in part, you relied upon information that was

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available to physicians during their training for your opinion about their knowledge -- well, strike all that.

In coming to the opinion that doctors were aware of certain risks and warnings that are contained in the IFU, what material did you rely upon?

A. Core textbooks, meetings, lectures, papers, clinical experience.

Q. And the doctors that we're referring to is not the foot surgeon down the street; right?

A. No.

Q. We're talking about doctors who are experienced in performing pelvic floor surgeries; correct?

A. Right; urologists, urogynecologists, gynecologists.

Q. And, in fact, the IFU indicates that those should be the users of the device; is that correct?

MR. FAES: Object to form.

A. Well, yes, but those who are familiar with pelvic floor anatomy and surgeries of the pelvic floor.

Q. Sure. So not just any gynecologist, but a

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gynecologist who is out there performing pelvic floor surgery; correct?

A. Yes.

Q. Mr. Faes asked you some questions about whether you knew for a hundred percent certainty that every doctor who performed procedures were aware of every single complication; correct?

MR. FAES: Object to form.

A. Yes.

Q. And, of course, you don't have -- you can't get inside of a physician's head to know exactly what they knew when, where and how; correct?

A. No, that's not possible for me to do that.

Q. But you are familiar with the type of training a urologist and a female pelvic floor surgeon as yourself goes through prior to performing any pelvic floor surgery; correct?

A. Yes.

MR. FAES: Object to form.

Q. You go to meetings that other surgeons who perform pelvic floor surgeries go to; is that correct?

A. I do.

Q. You review journals and literature that other

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surgeons who perform female pelvic floor surgeries review; is that correct?

A. Yes.

Q. And are you also relying upon that body of information, your education, training and experience and your encounters with your colleagues, as well as your education of current doctors to be surgeons in the future, in stating your opinion that you believe that the IFUs are adequate for use with the Gynemesh PS and Prolift devices?

MR. FAES: Object to form.

A. Yes, I agree based on what you had mentioned, my education, skills, training, courses, literature review.

Q. And your knowledge of what the other doctors go through; correct?

MR. FAES: Object to form.

A. Yes.

Q. Mr. Faes asked you some questions about whether the amount of mesh had an impact on the intensity and duration of fibrotic -- foreign body reaction; correct?

A. Yes.

Q. And you recall that line of questions?

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A. I do.

Q. The fact that a woman may have more mesh in her body than a woman who has a TVT procedure or sling procedure, for example, does that fact necessarily correlate to an adverse clinical impact for the woman who has the larger amount of mesh in her body?

MR. FAES: Object to form.

A. No, not necessarily.

Q. Are there other factors that affect the intensity and duration of a foreign body reaction?

A. Yes.

Q. And are those patient-type factors?

A. Yes. Like their age, whether they're a smoker, how much prolapse that they have, what prior surgeries they've had from below or from above, how many of those surgeries that they've had, how many vaginal deliveries they've had, whether they had a hysterectomy or not.

Q. Do those same -- are you done? I didn't mean to interrupt you.

A. Yes.

Q. Do those same factors also weigh in to the foreign body reaction that those women may have to a

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cadaveric tissue implant or other biologic-type implant?
A. They can have foreign body reaction to any of these. This is well described in the literature by Woodruff and also a paper by Daniel Elliot in rabbits.
Q. Mr. Faes asked you a few questions about what standard you used to determine whether a product is safe and effective. Do you recall that general line of questions?
A. Yes.
Q. Do you cover in your report your opinion on the safety and effectiveness of the Gynemesh device?
MR. FAES: Object to form.
A. Yes, in a small section.
Q. And do you cover in your report your opinion with regard to safety and effectiveness of the Prolift device in your report?
A. In extensive detail.
Q. Okay. And the literature that you discuss, does it -- did the literature -- strike that.
The literature that talks about the Prolift device, does it also necessarily include discussion of the Gynemesh PS mesh itself?

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MR. FAES: Object to form.
A. It may. I have to look at the specific papers of that.
Q. Okay. When -- I believe you stated this earlier in your testimony, but when you used the Prolift device, you essentially are delivering the Gynemesh PS into the pelvic floor of a woman; correct?
A. Yes.
Q. And the Gynemesh PS is what stays in a woman's pelvic floor; correct?
A. Yes.
Q. So literature that describes the risks and complications of the Prolift, would you agree that those are necessarily describing the risks and complications of the Gynemesh PS mesh itself?
MR. FAES: Object to form.
A. They certainly can.
Q. And did you rely upon -- well, what did you rely upon in forming your opinions that the Prolift device is safe and effective?
A. Review of the pertinent literature, papers, book chapters, personal experience, discussion with colleagues, the IFU.

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Q. When we talk about a device as being safe and effective, are we essentially talking about a risk-benefit discussion?
A. Yes.
Q. And is that risk-benefit your standard for determining whether a device is safe and effective?
A. Yes.
Q. Now, Ethicon, in addition to having the IFU, provides -- makes training available to physicians; correct?
A. Yes.
Q. And you went to that training yourself; correct?
A. Yes.
Q. Did you find that training adequate and helpful?
MR. FAES: Object to form.
A. Yes.
Q. They've also published the surgeon's manual monograph, for example; correct?
A. They have, yes.
Q. And that's discussed in your report as well?
A. Right. Which I had at the time when it came out.

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Q. And did you find that helpful as well?
A. Yes.
MR. FAES: Object to form.
Q. Helpful information about the risks and complications of the device?
A. It was helpful, yes.
Q. Mr. Faes was asking you some questions about your own personal patient satisfaction rates; correct?
A. Yes.
Q. And as you told him, you haven't analyzed those rates in specific detail for your patients; correct?
A. I have not, no.
Q. But are you -- well, in offering your opinions that the Prolift and the Gynemesh PS provides good satisfaction for patients, in addition to your clinical experience, are you relying upon any other information for that?
A. Certainly the literature, the papers that have come out over the years, information from colleagues, discussion at meetings.
Q. So I want you to look at, for example, page 38 in your report. You got a paragraph there

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that starts with, "As demonstrated in the level 1 RCTs comparing Prolift to traditional prolapse repairs"?
A. Yes.
Q. "No statistically significant difference in vaginal."
(Court reporter interrupts.)
Q. "As demonstrated in the level 1 RCTs comparing Prolift to traditional prolapse repairs, there was no statistically significant difference in vaginal length, de novo dyspareunia, sexual function, pelvic pain or quality of life." Do you see that?
A. I do, yes.
Q. And you cite a number of different randomized control trials supporting those conclusions; correct?
A. Yes, I do.
Q. And is that information also information that you're relying upon for your opinions that patient satisfaction is high with the Prolift and Gynemesh PS devices?
A. Yes.
Q. And Doctor, you indicated before Prolift came

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out, you were performing prolapse surgeries in a number of different ways; is that correct?
A. Yes.
Q. And since Prolift is no longer available, you've gone back to doing some of those surgeries; is that correct?
A. Yes.
Q. And, in fact, you assist in surgeries doing abdominal sacrocolpopexy; is that correct?
A. Yes.
Q. Do you believe that the -- if you had a choice in your patient between an abdominal sacrocolpopexy and a Prolift procedure, which one would you choose?
A. Certainly it would depend on the patient and their prior surgical or medical history. So say a patient who has had prior abdominal surgery who has a high body mass index, they would be better served with a vaginal procedure like a Prolift. The risk in such a patient for small bowel obstructions, adhesions, bowel injury, hernia, can be very high.
Q. Do you agree there are higher comorbidities with the abdominal sacrocolpopexy?
A. Yes.

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Q. With a patient with a cystocele defect, would you want to offer her the Prolift device today?
A. I would certainly, yes. If it were available.
Q. Did you find when you were -- strike that.
MS. ROBINSON: That's all the questions I have.
MR. FAES: I just have like three quick follow-up.

EXAMINATION
BY MR. FAES:
Q. Doctor, earlier defense counsel was asking you about a section of your report regarding the IFU on page 50 where 21 CFR 801.109(c) is cited?
A. Yes.
Q. Is that the only objective standard you're relying on for your opinion regarding the sufficiency of the IFU?
MS. ROBINSON: Object to form.
A. Again, I'm not a regulatory expert. I have looked at that in some detail, and that is my opinion. That manufacturers can omit warning information that would be commonly known to

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practitioners that are licensed to use that device, physicians to use that device in this case.
Q. What does CFR stand for?
A. CFR, I don't remember. Something -- I think R was regulatory. I don't remember what the CF stands for.
Q. How did you get that standard? Was that provided to you by counsel?
A. It was, yes, and then I reviewed what that was.
Q. So it's not any standard that you encountered on your own through your own independent research?
A. No.
Q. Are you aware of any other standards that state that any adverse reaction associated with a medical device must be included in the IFU regardless of whether or not a causal association has been proven?
A. You know, I'm not a regulatory expert, so no, I'm not aware.
MR. FAES: No further questions.

(Signature was waived.)
(Whereupon, the above-entitled matter

was concluded at 7:06 p.m., this date.)

STATE OF WEST VIRGINIA)
COUNTY OF OHIO)

I, Constance Lee, Registered Professional Reporter and Notary Public in and for the State of West Virginia, do hereby certify that the witness was first duly sworn to testify the truth, the whole truth, and nothing but the truth; that the foregoing deposition was taken at the time and place stated herein; and that the said deposition was recorded stenographically by me and then reduced to typewriting under my direction, and constitutes a true record of the testimony given by said witness, all to the best of my skill and ability.

I further certify that the inspection, reading and signing of said deposition were waived by counsel for the respective parties and by the witness.

I further certify that I am not a relative, or employee of either counsel, and that I am in no way interested, directly or indirectly, in this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office this 22nd day of March, 2017.

_____
Constance Lee, RPR, CSR(IL)
NCRA Realtime Systems Administrator